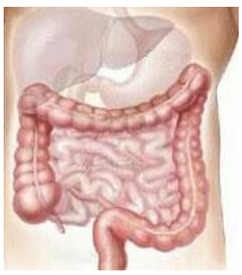
COLORECTAL CANCER RESEARCH UPDATES

Month Ending September 15th, 2017



The following colorectal cancer research update extends from July 13th to September 15th, 2017 inclusive and is intended for informational purposes only.

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DRUGS / SYSTEMIC THERAPIES

1. First-line cetuximab vs bevacizumab plus chemotherapy in KRAS wild-type colorectal cancer (Sept 10/17)

A phase III trial has found no significant difference in overall survival with first-line cetuximab (Erbitux) vs bevacizumab (Avastin) plus chemotherapy in patients with advanced or metastatic KRAS wild-type colorectal cancer (CRC). Erbitux is a monoclonal antibody therapy which inhibits the epidermal growth factor receptor (EGFR) implicated in metastatic CRC. Avastin is a monoclonal antibody and an anti-angiogenesis drug which inhibits the development of new blood vessels necessary for tumour growth. In the trial, 1,137 patients were enrolled at National Clinical Trial Network sites in the United States and Canada between November 2005 and March 2012. Patients chose to receive either FOLFOX6 treatment (leucovorin, fluorouracil, and oxaliplatin) or FOLFIRI (leucovorin, fluorouracil, and irinotecan) and were randomly assigned to receive either cetuximab or bevacizumab. Median overall survival was 30 months in the cetuximab group vs 29 months in the bevacizumab group. Median progression-free survival was 10.5 months vs 10.6 months. It was concluded that among patients with KRAS wild-type untreated advanced or metastatic CRC, there is no significant difference in overall survival between the addition of cetuximab and bevacizumab to chemotherapy as first-line treatment.

http://www.ascopost.com/issues/september-10-2017/first-line-cetuximab-vs-bevacizumab-plus-chemotherapy-in-kras-wild-type-colorectal-cancer/

2. Labetuzumab Govitecan in heavily pretreated patients with metastatic colorectal cancer (Sept 1/17)

A recent study demonstrated that the antibody-drug conjugate (ADC) labetuzumab govitecan had anti-tumour activity in a phase I/II trial among patients with heavily pretreated metastatic colorectal cancer (mCRC) who have already been treated with irinotecan. Labetuzumab govitecan is a therapy which combines an antibody (anti-carcinoembryonic antigen-related cell adhesion molecule (CEACAM5)) with the active breakdown product of irinotecan (SN-38). The study included 86 patients who had at least one previous irinotecan-containing therapy and had undergone an average of five prior therapies. The patients received labetuzumab govitecan once a week at 8 or 10mg/kg or two times per week at 4 or 6mg/kg on weeks 1 and 2 of 3-week cycles. It was observed that 38% of patients demonstrated both tumour reduction and reduction in plasma carcinoembryonic antigen level, a marker which is used as an indicator for the presence of certain kinds of cancer especially colorectal cancers. Stable disease was reported in 42 patients. Median progression-free and overall survival were 3.6 and 6.9 months, respectively. The most common adverse effects of the therapy were neutropenia (16%), leukopenia (11%), anemia (9%), and diarrhea (7%). The researchers concluded that therapy with labetuzumab govitecan demonstrated a manageable safety profile and therapeutic activity in heavily pretreated patients with mCRC. Further investigation of this treatment alone or used in combination with other therapies in earlier stages of the disease is necessary.

http://www.ascopost.com/News/57992

3. More support for FOLFOXIRI/bevacizumab in advanced colorectal cancer (Aug 10/17)

Results from the German CHARTA trial found that a FOLFOXIRI regimen (fluorouracil/leucovorin, oxaliplatin, irinotecan) plus bevacizumab (Avastin) was more effective in treating patients with advanced colorectal cancer (CRC) compared to a regimen of FOLFOX (fluorouracil/leucovorin, oxaliplatin) plus bevacizumab as first-line treatment. Currently, the regimen of FOLFOX plus bevacizumab is one of the more commonly used first-line treatments in cases of advanced CRC, despite having limited effectiveness. The CHARTA study included 242 patients who received either FOLFOX plus bevacizumab or FOLFOXIRI plus bevacizumab. Patients underwent 6 months of chemotherapy, then maintenance therapy with capecitabine plus bevacizumab for up to 12 months. Results demonstrated a significantly improved progression-free survival at 9 months among patients who were given the FOLFOXIRI/bevacizumab regimen: 68% compared to 56% among patients given FOLFOX/bevacizumab. Median progression-free survival improved by 20% in the FOLFOXIRI/bevacizumab group compared to the FOLFOX/bevacizumab group. It was also found that FOLFOXIRI/bevacizumab's effect was the most pronounced among RAS wild-type tumours. With respect to toxicity, the regimen was well tolerated among patients, with no increase in clinically relevant toxicity even among patients up to 82 years old. The main adverse effects were higher incidence of diarrhea and more hematologic toxicity with the FOLFOXIRI regimen. Despite these effects, the FOLFOXIRI regimen scored slightly better on the Quality of Life Global Health Scores compared to the FOLFOX regimen.

http://www.ascopost.com/issues/august-10-2017/more-support-for-folfoxiribevacizumab-in-advanced-colorectal-cancer/

4. Nivolumab in advanced DNA mismatch repair-deficient or microsatellite instability-high colorectal cancer (Aug 4/17)

Results from the CheckMate 142 phase II trial demonstrated that nivolumab (Opdivo) produces lasting responses among patients with recurrent or metastatic DNA mismatch repair-deficient (dMMR)/microsatellite instability-high (MSI-H) colorectal cancer. Nivolumab is a targeted antibody therapy which blocks the human programmed death receptor -1 (PD-1). The study included 74 patients with recurrent or metastatic colorectal

cancer locally assessed as dMMR/MSI-H. Patients received nivolumab at 3mg/kg every 2 weeks until disease progression or unacceptable toxicity. Overall, 54% of patients had received 3 or more previous treatments. At a median follow-up of 12 months, objective response was reached in 23 patients with an additional 28 having stable disease for 12 weeks or longer. 12-month progression-free survival was 50%, and 12-month overall survival was 73%. 54% of patients experienced grade 3 or 4 adverse events, the most common being increased lipase (8%) and amylase (3%). Researchers concluded that nivolumab provided lasting responses and disease control in pretreated patients with dMMR/MSI-H metastatic colorectal cancer and is a new possible treatment option for patients with this disease.

http://www.ascopost.com/News/57899

5. Hepatic Artery Infusion Pump (HAIP) Chemotherapy Program – Sunnybrook Odette Cancer Centre

The HAIP program is a first-in-Canada for individuals where colon or rectal cancer (colorectal cancer) has spread to the liver and cannot be removed with surgery. The program involves a coordinated, multidisciplinary team approach to care, with close collaboration across surgical oncology, medical oncology (chemotherapy), interventional radiology, nuclear medicine, and oncology nursing. The Hepatic Artery Infusion Pump (HAIP) is a small, disc-shaped device that is surgically implanted just below the skin of the patient, and is connected via a catheter to the hepatic (main) artery of the liver. About 95 percent of the chemotherapy that is directed through this pump stays in the liver, sparing the rest of the body from side effects. Patients receive HAIP-directed chemotherapy in addition to regular intravenous (IV) chemotherapy (systemic chemotherapy), to reduce the number and size of tumours.

Presently at Sunnybrook Odette Cancer Centre, HAIP is only being used in patients with colorectal cancer that has spread to the liver that cannot be removed surgically, and has not spread to anywhere else in the body. Patients who have few (1-5) and very small tumors in the lungs may be considered if the lung disease is deemed treatable prior to HAIP. If you believe you may benefit from this therapy and/or would like to learn more about the clinical trial, your medical oncologist or surgeon may fax a referral to **416-480-6179**.

http://sunnybrook.ca/content/?page=colorectal-colon-bowel-haip-chemotherapy

6. Imaging and biomarker test could more accurately predict longer-term patient response to Regorafenib in colorectal cancer (Aug 14/17)

A new study published in *Gut* suggests that a magnetic resonance imaging (MRI) scan and a blood test administered among patients with metastatic colorectal cancer (mCRC) may help to identify those who would benefit from a targeted cancer treatment. It was observed that after 2 weeks on the drug regorafenib (Stivarga), an MRI scan could help select patients who would respond an average of 9.4 months longer than patients who did not respond to treatment. Furthermore, the use of a blood test which scans for cancer DNA also tracked the benefit of treatment, whereby patients with lower levels of cancer DNA after 2 months survived an average of 9.7 months longer than patients who had no change in cancer DNA levels at all. The study findings suggest that the combination of the MRI scan with the blood test could be a quick prediction of which patients will respond to treatment, allowing doctors to identify the patients who are no longer benefiting from the treatment and get them on an alternative treatment plan as soon as possible. The study examined 27 patients with chemotherapy-resistant advanced CRC with KRAS mutations who were participating in a phase II clinical trial of regorafenib. Regorafenib is a drug which inhibits blood supply to tumours, cutting them off from vital nutrients and oxygen that they need in order to proliferate. Using MRI, researchers were able to assess whether the drug was indeed affecting the tumour targets by observing the reduction in blood vessels reaching the tumour. Patients who responded to the drug and showed a reduction in tumour blood supply by 70% survived 6 months on the treatment, and 75% were alive after one year. These patients survived an average of 15.2 months, compared to 5.8 months among patients who did not respond to regorafenib. Researchers also found that patients who responded to regorafenib had a significant decrease in circulating tumour DNA (ctDNA). 48% of the 27 patients experienced a marked drop in ctDNA for 2 months, and survived 15.2 months after beginning treatment compared to 5.5 months survival for patients who did not have any marked decline in blood ctDNA levels. The use of these two tests provides promising results in identifying patients who are likely to respond to treatment and those who are not, thereby guiding further clinical decisions with more confidence. Further trials will commence among a larger patient group that will assess these tests in succession.
http://www.ascopost.com/News/57922

SURGICAL THERAPIES

7. Living donor liver transplantation for unresectable colorectal cancer liver metastases (May 2017)

Approximately half of all colorectal cancer (CRC) patients develop metastases, commonly to the liver and lung. Surgical removal of liver metastases (LM) is the only treatment option, though only 20-40% of patients are candidates for surgical therapy. Surgical therapy adds a significant survival benefit, with a 5-year survival after liver resection for LM of 40-50%. Liver transplantation (LT) would remove all evident disease in cases where the colorectal metastases are isolated to the liver but considered unresectable. While CRC LM are considered a contraindication for LT at most cancer centers, a single center in Oslo, Norway demonstrated a 5-year survival of 56%. A clinical trial sponsored by the University Health network in Toronto will offer live donor liver transplantation (LDLT) to select patients with unresectable metastases limited to the liver and are non-progressing on standard chemotherapy. Patients will be screened for liver transplant suitability and must also have a healthy living donor come forward for evaluation. Patients who undergo LDLT will be followed for survival, disease-free survival and quality of life for 5 years and compared to a control group who discontinue the study before transplantation due to reasons other than cancer progression.

https://clinicaltrials.gov/ct2/show/NCT02864485

NUTRITION/ HEALTHY LIFESTYLE

8. A Phase III study of the impact of a physical activity program on disease-free survival in patients with high risk stage II or stage III colon cancer: a randomized controlled trial (CHALLENGE)

The purpose of this study is to compare the disease-free survival of patients involved in a physical activity program (designed to increase physical activity participation) who also receive general health education materials (about diet and physical activity) to patients who receive the general health education materials only. This study is being done because, as of yet, there is no conclusive evidence that physical activity will decrease the likelihood of colon cancer recurrence. This study will also obtain important information about the impact of physical activity on patients' physical functioning, body composition, quality of life, fatigue, mood, cytokines and the insulin pathway, and their influence on prognosis, as well as cost-effectiveness.

Eligibility: Medically fit colon cancer patients (high risk stage II and stage III) who have completed adjuvant chemotherapy within the past 60-180 days. Current physical activity levels must not meet the recommended guidelines (>=150 minutes of moderate-to-vigorous or >=75 minutes of vigorous exercise/week). Following registration, and prior to randomization, patients must successfully complete at least two stages of a submaximal exercise test to ensure they are able to safely exercise at a moderate to vigorous intensity.

Participation: Limited to invited centres.

For more information, visit the link below:

https://scooby.ctg.queensu.ca/tum_bank/tum.php?g_cmd=trial_info&g_trial_cd=CO21

9. Cancer Prevention Recommendations: Cancer Prevention Recommendations World Cancer Research Fund International (WCRFI)

The WCRFI's Continuous Update Project (CUP) is an ongoing program that analyzes the latest global research on how diet, nutrition, physical activity and weight impact cancer risk and survival. Their report on colorectal cancer was published in September 2017 and is the most systematic, global analysis of the currently available scientific research available on diet, weight, physical activity and **colorectal cancer** risk and outcomes. Key findings from the report include:

- being physically active decreases the risk of colon cancer
- consuming wholegrains decreases the risk of colorectal cancer
- consuming foods containing dietary fibre decreases the risk of colorectal cancer
- consuming dairy products decreases the risk of colorectal cancer
- taking calcium supplements decreases the risk of colorectal cancer
- consuming red meat increases the risk of colorectal cancer
- consuming processed meat increases the risk of colorectal cancer
- consuming approximately two or more alcoholic drinks per day increases the risk of colorectal cancer
- being overweight or obese increases the risk of colorectal cancer
- being tall increases the risk of colorectal cancer

The WCRFI's analysis of global research demonstrates that about a third of the most common cancers are preventable through a nutritious diet, maintaining a healthy weight and regular physical activity. The following are their recommendations:

Plant foods – eat more grains, veg, fruit and beans

The WCFRI has set the following public health goals:

- Population average consumption of non-starchy[1] vegetables and of fruits to be at least 600 g (21 oz) daily[2]
- Relatively unprocessed cereals (grains) and/or pulses (legumes), and other foods that are a natural source of dietary fibre, to contribute to a population average of at least 25g non-starch polysaccharide daily

A diet made up of mostly foods of plant origin is ideal. The WCRFI suggestions include:

- Eat at least five portions/servings (at least 400 g or 14 oz) of a variety[2] of non-starchy vegetables and of fruits every day
- Eat relatively unprocessed cereals (grains) and/or pulses (legumes) with every meal[3]
- Limit refined starchy foods
- People who consume starchy roots or tubers[4] as staples also to ensure intake of sufficient non-starchy vegetables, fruits, and pulses (legumes)

1. This is best made up from a range of various amounts of non-starchy vegetables and fruits of different colors including red, green, yellow, white, purple, and orange, including tomato-based products and allium vegetables such as garlic

2. Relatively unprocessed cereals (grains) and/or pulses (legumes) to contribute to an average of at least 25g non-starch polysaccharide daily

3. These foods are low in energy density and so promote healthy weight

4. For example, populations in Africa, Latin America, and the Asia-Pacific region

Image from: https://www.forksoverknives.com

Body fatness – keep weight low within the healthy range

There is strong evidence that demonstrates how weight gain, overweight and obesity increase the risk of 11 cancers, including colorectal cancer. Maintaining a healthy weight – through a balanced diet and regular physical activity – helps reduce the risk of developing cancer. Our recommendation is to be as lean as possible within the normal range[1] of body weight.

Public health goals include:

- Median adult body mass index (BMI) to be between 21 and 23, depending on the normal range for different populations[2]
- The proportion of the population that is overweight or obese to be no more than the current level, or preferably lower, in 10 years

Personal recommendations:

- Ensure that body weight through childhood and adolescent growth projects[3] towards the lower end of the normal BMI range at age 21
- Maintain body weight within the normal range from age 21
- Avoid weight gain and increases in waist circumference throughout adulthood

[1] 'Normal range' refers to appropriate ranges issued by national governments or the World Health Organization

[2] To minimize the proportion of the population outside the normal range

[3] Projects' in this context means following a pattern of growth (weight and height) throughout childhood that leads to adult BMI at the lower end of the normal range. Such patterns of growth are specified in International Obesity Task Force and WHO growth reference charts

Physical activity – be physically active for at least 30 minutes per day, and sit less

Public health goals:

- The proportion of the population that is sedentary[1] to be halved every 10 years.
- Average physical activity levels (PALs) 1 to be above 1.6

Personal recommendations:

- Be moderately physically active, equivalent to brisk walking,[2] for at least 30 minutes every day
- As fitness improves, aim for 60 minutes or more of moderate, or for 30 minutes or more of vigorous, physical activity every day[2,3]
- Limit sedentary habits such as watching television

[1.] The term 'sedentary' refers to a PAL of 1.4 or less. PAL is a way of representing the average intensity of daily physical activity. PAL is calculated as total energy expenditure as a multiple of basal metabolic rate

[2.] Can be incorporated in occupational, transport, household, or leisure activities

[3]This is because physical activity of longer duration or greater intensity is more beneficial

Animal foods – limit red meat and avoid processed meat

Public health goals:

- Population average consumption of red meat to be no more than 300 g (11 oz) a week, very little if any of which to be processed

Personal recommendations:

- People who eat red meat[1] to consume less than 500 g (18 oz) a week, very little if any to be processed[2]

[1.] 'Red meat' refers to beef, pork, lamb, and goat from domesticated animals including that contained in processed foods

Alcoholic drinks – for cancer prevention, don’t drink alcohol

Public health goals:

- Proportion of the population drinking more than the recommended limits to be reduced by one third every 10 years[1]

Personal recommendations:

- For cancer prevention, it’s best not to drink alcohol. If you do, limit alcoholic drinks and follow national guidelines[1]

[1.] Children and pregnant women not to consume alcoholic drinks

OTHER

10. Study finds gut microbes may promote immune responses against colorectal cancer (Sept 7/17)

A recent study aimed to investigate the interactions between gut microbes and signalling proteins in enabling the infiltration of beneficial immune cells to sites of colorectal cancer (CRC). Researchers found that gut microbiota stimulate the production of signalling proteins known as chemokines which recruit immune T cells to the tumour, which may be associated with better disease outcomes. The researchers examined the expression of chemokines, chemokine receptors and immune cell markers among 62 human colorectal cancers and healthy colon tissue. They found that the infiltration by immune cells at sites of CRC was associated with the presence of numerous chemokine genes including CCL5, CXCL9, T-helper 1 cells and regulatory T cells. Most of these chemokine genes were expressed by the CRC tumour cells upon exposure to gut bacteria in vitro and in vivo. The expression levels were drastically reduced by antibiotic treatment of CRC tumour-bearing mice, suggesting a role for these "good" bacteria in inducing chemokine expression. Additionally, the extent of T-cell infiltration into tumour cells was significantly correlated with bacterial load. Researchers suggest that the findings may open the doors toward the development of new treatments targeting the gut flora to promote better infiltration of CRC tumours by immune cells which display antitumour effects – for example, bacterial transplantation prior to immunotherapy to boost success rates.

http://www.ascopost.com/News/58006

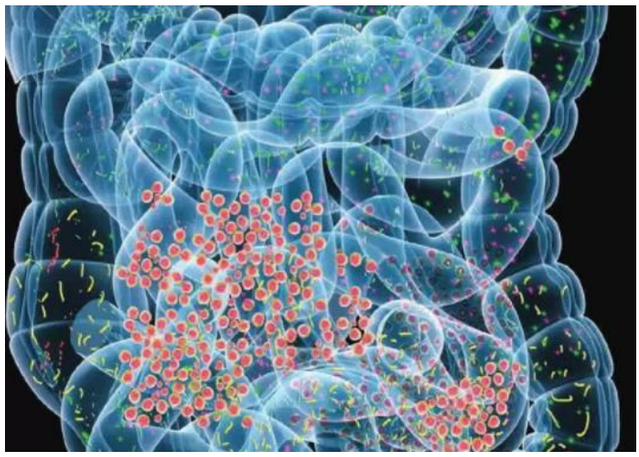

Image from: http://neurosciencenews.com/microbiota-alzheimers-6096/http://neurosciencenews.com/microbiota-alzheimers-6096/

11. Colorectal cancer mortality rates in adults aged 20 to 54 years from 1970 to 2014 (Aug 15/17)

Between 1970 and 2014, overall colorectal cancer mortality rates have declined in the United States among patients aged 20 to 54 years old, but have increased among white individuals in this age group between 2004 and 2014. The study by Siegel et al. found that colorectal cancer mortality per 100,000 declined from 6.3 in 1970 to 3.9 in 2004 among individuals aged 20 to 54 years. This rate, however, increased by 1% annually to 4.3 in 2014. The increase was limited to white individuals, who experienced an increase by 1.4% annually from 3.6 in 2004 to 4.1 in 2014. Mortality rates in black individuals decreased by 0.4% annually from 8.1 in 1970 to 6.1 in 2014. Mortality rates decreased in individuals of other races by 1.1% between 1970 and 2006 and experienced no significant change thereafter. Researchers concluded that rising mortality rates in young and middle-aged adults indicate the need for earlier colorectal cancer screening and awareness through age-appropriate screening and more timely follow-up of symptoms.

http://www.ascopost.com/News/57932

12. Study identified factors that link work ability of young cancer survivors (Sept 9/17)

The NOR-CAYACS study examined the work ability of patients who were diagnosed with cancer between the ages of 19 and 39 years of age. Even after the end of cancer treatment, side effects can occur months or even years later and may interfere with an individual's career development. The study followed patients diagnosed with melanoma, colorectal cancer, breast cancer, non-Hodgkin's lymphoma or leukemia from 1985 to 2009. A total of 1198 patients filled out a questionnaire about the late effects of treatment and work status, scoring themselves 0 (no work ability) to 10 (highest work ability) on the Work Ability Index. A low score on the Work Ability Index was linked to a lower level of education, female sex, fatigue, depression and reduced physical quality of life and self-reported health. Treatment intensity was not associated with work ability. Researchers observed that late onset psychological and physical effects of cancer were significantly associated with reduced work ability, while treatment intensity and cancer type were not significantly related to work ability. They concluded that young cancer survivors should be informed about the potential late toxicities of treatment and closely monitored to minimize the severity of long-term side effects. Another related study revealed that more than two-thirds of healthcare providers treating adolescents and young adults with cancer in Europe had no access to specialized centres with expertise in the management of late effects of cancer treatment in this group. The study results were collected from a survey on the status of care

and research in this subset of patients, completed by members of this patient group as well as several European oncology groups. The study showed that most respondents were able to refer young patients to psychological support and social work resources, and almost 50% had access to nursing services tailored to their age group. 38% of respondents said young cancer patients had no access to fertility specialist, a percentage which rose to 76% among Eastern European respondents. Researchers indicate that these patients have specific needs that are not covered by paediatric or general oncology centres, highlighting that most do not have access to the recommended specialty care. Researchers suggest looking at existing examples such as in France and the UK in order to between equip teams to improve outcomes for adolescents and young adults with cancer.

https://m.medicalxpress.com/news/2017-09-factors-limit-ability-young-adult.html

13. Young adult colorectal cancer clinic now available at Sunnybrook

A recent study led by University of Toronto doctors has observed a rise in colorectal cancer rates in patients under the age of 50. The study mirrors findings from the U.S., Australia and Europe. The growing colorectal cancer rates in young people come after decades of declining rates in people over 50, which have occurred most likely due to increased use of colorectal cancer screening (through population-based screening programs) which can identify and remove precancerous polyps.

Patients diagnosed under the age of 50 have a unique set of needs, challenges and worries. They are unlike those diagnosed over the age of 50. **Dr. Shady Ashamalla (colorectal cancer surgical oncologist),** and his team at the **Sunnybrook Health Sciences Centre** understand the needs of this patient population. Dr. Ashamalla belongs to a multidisciplinary team of experts in the ***Young Adult Colorectal Cancer Clinic*** who will work with young colorectal cancer patients, regardless of disease stage, to create an individualized treatment plan to support each patient through their cancer journey. Their needs and concerns will be addressed as they relate to:

- Fertility concerns and issues
- Young children at home
- Dating/intimacy issues
- Challenges at work
- Concerns about hereditary cancer
- Relationships with family and friends
- Psychological stress due to any or all of the above

The team of experts consists of:

- Oncologists (medical, surgical, radiation)
- Social workers
- Psychologists
- Geneticists
- Nurse navigator

Should a patient wish to be referred to Sunnybrook, they may have their family doctor or their specialist **refer them to Sunnybrook via this e-referral form.** Once the referral is received, the **Young Adult Colorectal Cancer Clinic** will be notified if the patient is under the age of 50. An appointment will then be issued wherein the patient will meet with various members of the team to address their specific set of concerns.

http://sunnybrook.ca/content/?page=young-adult-colorectal-cancer-clinic

14. Sunshine: Vitamin D slows colon cancer progression (Jul 6/17)

Vitamin D is a fat-soluble vitamin which is necessary for bone health and according to some research, may also reduce the risk of certain types of cancer. Our bodies synthesize vitamin D through unprotected exposure to the sun and is obtainable through dietary supplements such as fortified milk and cereals and

certain kinds of fish (such as salmon, mackerel and tuna). Recently, data has shown that elevated vitamin D levels in the blood are linked to improved survival in colorectal cancer patients. The SUNSHINE clinical trial included patients with previously untreated metastatic colorectal cancer. All trial participants received the standard treatment of FOLFOX chemotherapy regimen (folinic acid, fluorouracil and oxaliplatin) plus bevacizumab (Avastin) and either a high or low dose of supplemental vitamin D. It was found that patients who received the high dose of vitamin D (dose of 8000 IU/day for 2 weeks followed by 4000IU/day) had a progression-free survival of approximately 2 months longer than the participants in the low-dose vitamin D group (a standard vitamin D3 dose of 400 IU/day). These study results suggest that vitamin D supplementation may be a promising complementary therapy in cancer treatment.

http://cancer.unm.edu/2017/07/06/sunshine-vitamin-d-slows-colon-cancer-progression/