

Final Report on Ecomer Use During Breast Cancer Treatment: A Randomized Double-Blind Placebo Controlled Study

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Introduction

Shark liver oil has a long history of traditional use and has been used since the 1200th century in northern Europe to increase the power of resistance to different diseases. A medical journal from Iceland (1830-1840) describes the positive effects of shark liver oil on respiratory problems. Alkylglycerols (AKG) are an important group of active substances in bone marrow and shark liver oil holds the highest concentration of natural alkylglycerols known in nature. In the beginning of 1950's, Dr. Astrid Brohult worked at a well-known hospital for children in Stockholm where she was very moved by, and concerned about the children suffering from leukaemia. Dr Astrid Brohult developed new ways to treat leukaemia in children. Her findings were the start of the development of ECOMER, first launched in 1986, today sold all over the world. Ecomer is a soft gelatine capsule containing 250mg of shark liver oil with 20% AKG.

Dr Brohult noticed that when AKG were administered during cancer treatment the level of white blood cells and platelets did not fall quite as far and even increased if levels were already low due to radio or chemotherapy. Bone marrow cells were also protected and she observed less decrease in megacaryocytes and nucleated cells after irradiation. Promising results showed an increased survival rate at 1 and 5 years for 350 patients with cervix cancer when administered during radiation treatment.

Evidence of immune stimulating properties of AKG has been shown in a number of animal studies involving mother's breast milk, a rich source of AKG. Female rats fed with various concentrations of AKG from the day of conception to the day of delivery had a significant increase in milk AKG concentration. This increase

in AKG concentration in the mother's milk led to an increase in granulocytes and plasma immunoglobulins in the pups (1). A similar study was performed in lactating pigs where pregnant sows were given AKG from day 80 until weaning. The sows were vaccinated against Aujeszky's disease and the concentration of IgG and Aujeszky antibodies in the colostrum increased significantly. The concentration of leucocytes, IgG and Aujeszky antibodies increased in the piglets too. Both of these animal studies show that after supplementation with AKG the mother passes the immune boosting effects to the offspring through an increased AKG content and a boosted self immune system resulting in healthier offspring (2).

This report summarises the early findings in mice and a 13 year follow up of a placebo controlled double blind study in patients with breast cancer.

Results and Discussion

Initial trials in tumour bearing mice

Evidence of immune stimulating properties of AKG and specifically Ecomer led a leading oncologist, Professor Ingemar Näslund at Karolinska Institutet, to perform some pre-clinical experiments on tumour bearing mice. A study was set up where 48 mice received AKG in their feed (dose corresponding to 300mg in man) and 48 did not. The mice had either sarcoma or breast cancer xenografts and tumor growth was monitored twice weekly until max tumour size (20x20x20mm) or until death. The initial question in this study was, 'does the addition of AKG in mice feed reduce tumour growth?'

It was noticed that tumours on mice that were supplemented with AKG grew significantly slower than the control group and interestingly did not

even reach the size of the placebo group. This trend was observed in both sarcoma and breast cancer xenografts (Figure 1 A and B). In mice injected with breast cancer cells the survival rate of the mice were also extended with the supplementation of AKG. The survival rate was extended from 39.9 days to 48.3 days with a p value of 0.0131 (Figure 1C).

Figure 1.

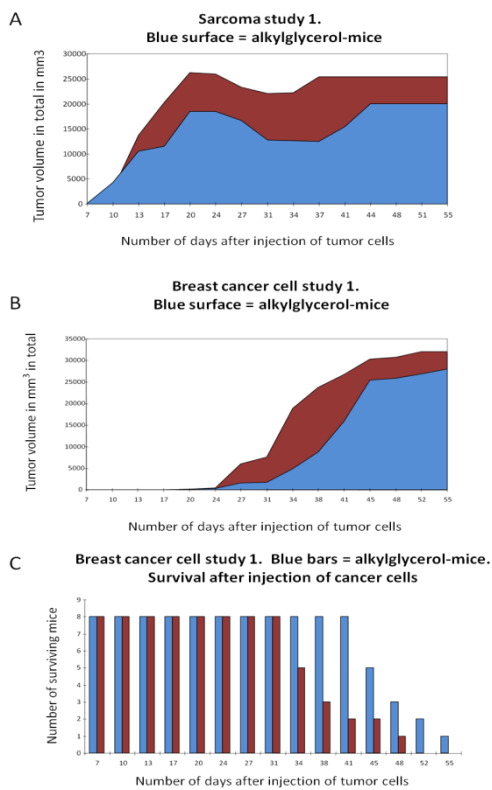


Figure 1. Tumor size over time in mice supplemented with or without Ecomer. A) Sarcoma, B) Breast cancer and C) Breast cancer survival.

Randomized, Double-Blind, Placebo Controlled Study

These promising pre-clinical data on the benefits of AKG supplementation with Ecomer in mice gave enough preliminary data to initiate a clinical trial in breast cancer patients. Going through the correct ethical approval methods a clinical trial was initiated in 1999 in patients with operated breast cancer and who were receiving CMF (cyclophosphamide and methotrexate and 5-fluorouracil) or FEC (5-fluorouracil, epirubicin and cyclophosphamide) treatments. The study was conducted as a randomized, double blind placebo controlled study. In total 105 patients were

recruited and all had begun treatment by the end of 2002. Patients received either capsules with shark liver oil or vegetable oil as a placebo for 6 months during their chemotherapy and follow up survival was monitored for 13 years.

The number of local recurrences was reduced in patients who took Ecomer supplementation during their treatment compared to the placebo group (Figure 2A). If the data is looked at from a different perspective Ecomer also gave rise to the number of patients free of local recurrences after 13 years compared to the placebo group (Figure 2B).

Figure 2.

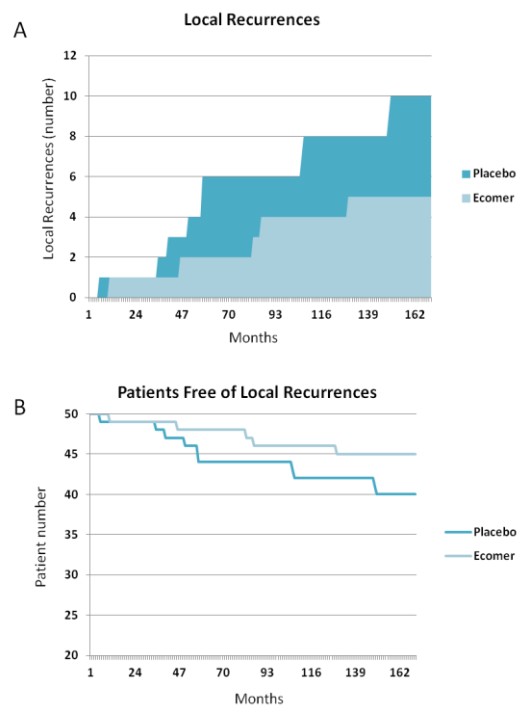


Figure 2. Randomized, placebo controlled double blind breast cancer study. Complete 13 year follow up of local recurrences. A) Local recurrences and B) Patients free from local recurrences.

Distant metastases are a big problem following cancer treatment but patients on Ecomer supplementation show a reduced number of distant metastases compared to the placebo group (Figure 3A). Likewise the number of patients free of metastases were greater in the Ecomer group compared to the placebo group after 13 years (Figure 3B).

Figure 3.

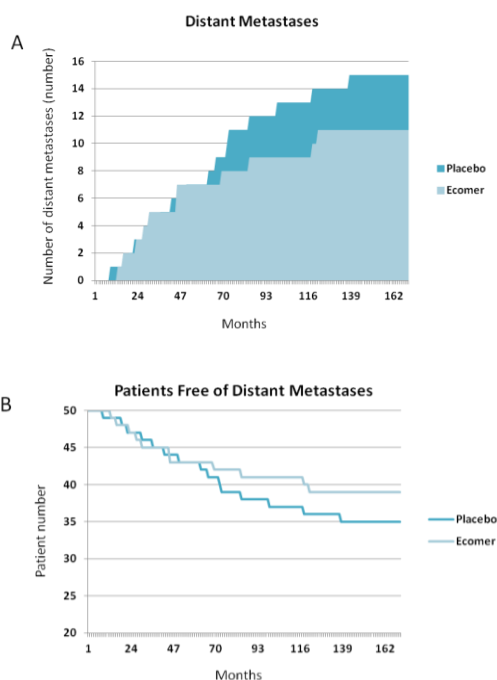


Figure 3. Randomized, placebo controlled double blind breast cancer study. Complete 13 year follow up of distance metastases. A) Distance metastases and B) Patients free from distance metastases.

Finally if we look at the total death rate during the trial Ecomer has a clear protective role to play in the cancer death rate versus the placebo (Figure 4A). The corresponding survival rates are also better with a 74% survival rate for Ecomer and a 68% survival rate for placebo.

Figure 4.

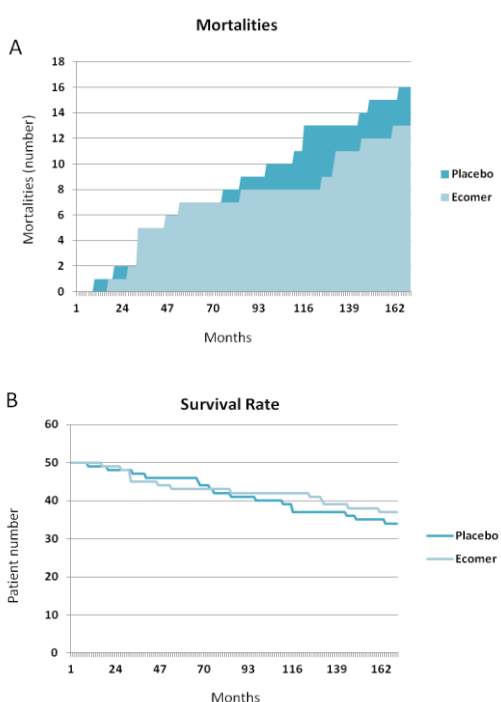


Figure 4. Randomized, placebo controlled double blind breast cancer study. Complete 13 year survival rates. A) Mortality rate and B) Survival rate.

Conclusion

The follow-up of all 105 patients during 13 years **indicates** that alkylglycerols in combination with chemotherapy in breast cancer **prolongs time to recurrences and increases the survival rate**. Due to the small number of patients it is not possible to show significant values. However, to get such strong trends emerging in such a small trial gives great confidence in the protective role of Ecomer in cancer treatment. One also has to remember that patients were only supplemented with Ecomer for 5-6 months during the treatment phase so results could have been much stronger with prolonged supplementation.

Looking at white blood cell counts in patients supplemented with either Ecomer or placebo it was evident that after the first round of chemotherapy the total white blood cell count dropped to a lower level with Ecomer supplementation. This may have been contradictory to what would have been expected but after the second round of treatment the Ecomer group responded with a higher white blood cell count than the placebo on recovery (Data not shown). Stimulatory effects were also seen on bone marrow in the Ecomer group. So overall patients supplemented with Ecomer had a lower dip in white blood cell count but a higher recovery after treatment which could be a reason for the positive trend observed in the study.

There were two incidences of thrombosis in the legs of patients during the study but both of these patients turned out to be on the placebo oil. No other adverse effects related to the Ecomer supplementation were noted.

The supplementation with shark liver oil has a strong history in Northern Europe and has a lot of documented health benefits. This study set out to evaluate Ecomer's benefits during and after cancer treatment. Today's methods of cancer treatment are large and varied due to the heterogeneity of cancers and drugs used. It cannot be concluded or advised to use Ecomer during chemotherapy or radiotherapy before larger studies with patients undergoing different

types of chemotherapy are performed. We can however advise the long term use of Ecomer after cancer treatment and during remission. Ecomer has proven immune boosting effects which may help the body combat any remaining cancer cells, reducing the risk of recurrence or metastases (Figure 5). This boost to the immune system when it is at its lowest could help the body rid itself of any remaining cancer cells before they can take hold again (3,4,6 and 7).

Figure 5.

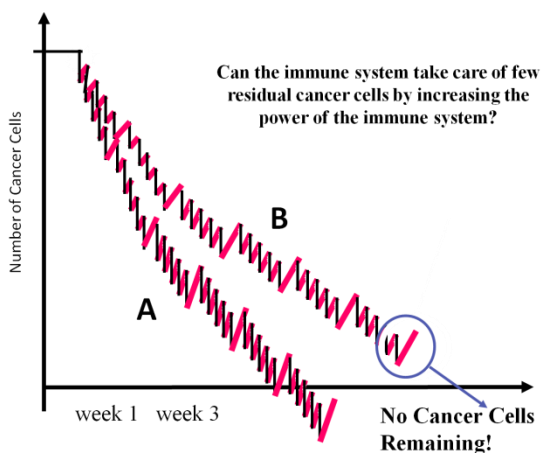


Figure 5. During chemotherapy and radiotherapy treatments the aim is to do just enough to eliminate the cancer without doing too much damage to the healthy cells (A). This desired line is often difficult to find and in many cases it can fall short leaving some cancer cells. If after treatment a few cancer cells remain these can re-grow and spread. Boosting the immune system with Ecomer after cancer treatment can help the body kill these cells (B).

As well as cancer treatment Ecomer should be used in cases of any pressure on the immune system such as infections and times of stress (5). Ecomer can provide an essential boost to the immune system during these times, reducing both the severity and the recovery time of illness (Figure 6).

Figure 6.

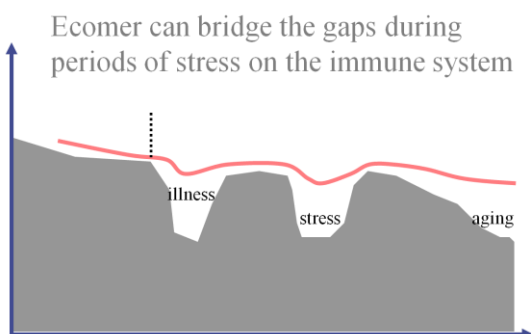


Figure 6. Ecomer can act as a bridge when the body's immune system is compromised such as illness, stress and aging.

References

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