

The Anti-Proliferative Effects of a Frankincense Extract in a Window of Opportunity Phase Ia Clinical Trial for Patients with Breast Cancer

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This is a preprint; it has not been peer reviewed by a journal.



<https://doi.org/10.21203/rs.3.rs-2050004/v1>

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Abstract



Background

Boswellic acids, the active components of frankincense, have been shown to suppress tumor proliferation and apoptosis in vitro with a strong clinical trial safety profile in patients with inflammatory diseases. We performed a Phase Ia window of opportunity trial of *Boswellia serrata* (*B. serrata*), the plant that produces frankincense, in patients with breast cancer to evaluate its biologic activity and safety.

Methods

This was a Phase Ia window of opportunity trial invasive breast cancer patients treated pre-operatively with *B. Serrata* (2400 mg/day PO) until the night before surgery. Paraffin-embedded sections from pretreatment diagnostic core biopsies were evaluated using a tunnel assay and immunohistochemistry staining with Ki-67 antibodies. A non-intervention control arm consisted of core and surgical tissue specimens from untreated patients was used to compare to patients treated with *B. Serrata*. The change in proliferation and apoptosis between diagnostic core specimens and specimens obtained at surgery was compared between the control and treatment groups using a two-tailed paired t-test.

Results

There was an increase in percent change in proliferation from core biopsy to surgical excision in the control group (n = 18) of $54.6 \pm 21.4\%$. In the *B. serrata*-treated group there was a reduction in proliferation between core biopsy and excision (n = 18) of $13.8 \pm 11.7\%$. The difference between core and surgical specimens was statistically significant between the control and *B. serrata*-treated groups (p = 0.008). There was no difference in change in apoptosis. There were no serious adverse events related to the drug.

Conclusion

Boswellia serrata inhibited breast cancer proliferation in vivo in a clinically well-tolerated Phase Ia window of opportunity trial.

Trial registration: ClinicalTrials.gov. Identifier NCT03149081, date of registration May 11, 2017

Boswellia serrata

breast neoplasm

natural products

Figures



Background



Methods



Results



Discussion



Abbreviations



Declarations



References



Competing Interests

