

PERIOP:06

*A Phase II Study of Perioperative
QBECO Site Specific
Immunomodulator (Qu Biologics®)
in Patients with Metastatic
Colorectal Adenocarcinoma within
the Liver Undergoing Resection*

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Perioperative Care Network



RFA 3 – Canadian Biotech/RCTs



Evaluating Canadian Biotech with RCTs

- Company: Qu Biologics Inc.
- IP: QBECO (SSI)
- Therapeutic area: Colorectal Liver Metastases



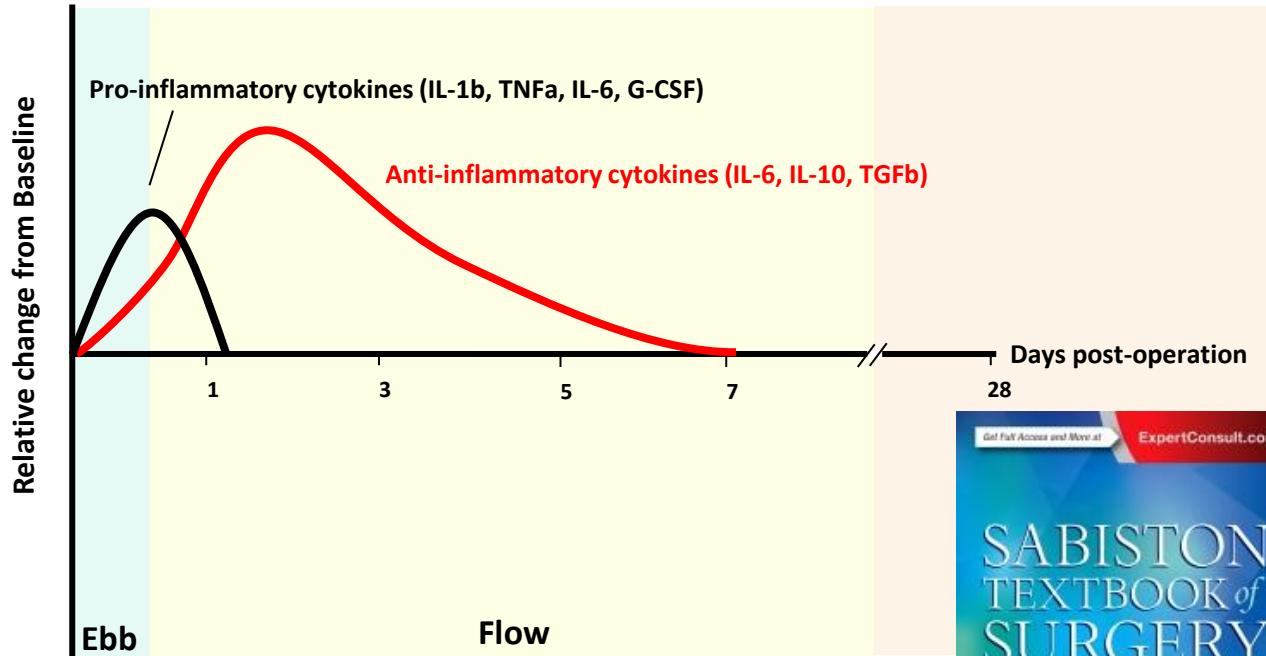
Research Question

Primary Objective

The primary objective of this randomized controlled trial (RCT) is to determine if QBECO administered perioperatively can improve PFS in adult patients undergoing resection of CRLMs for complete clearance of metastatic disease.

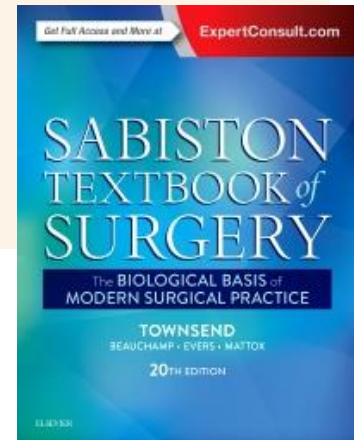


Postoperative Recovery: The “ebb” and the “flow” phases

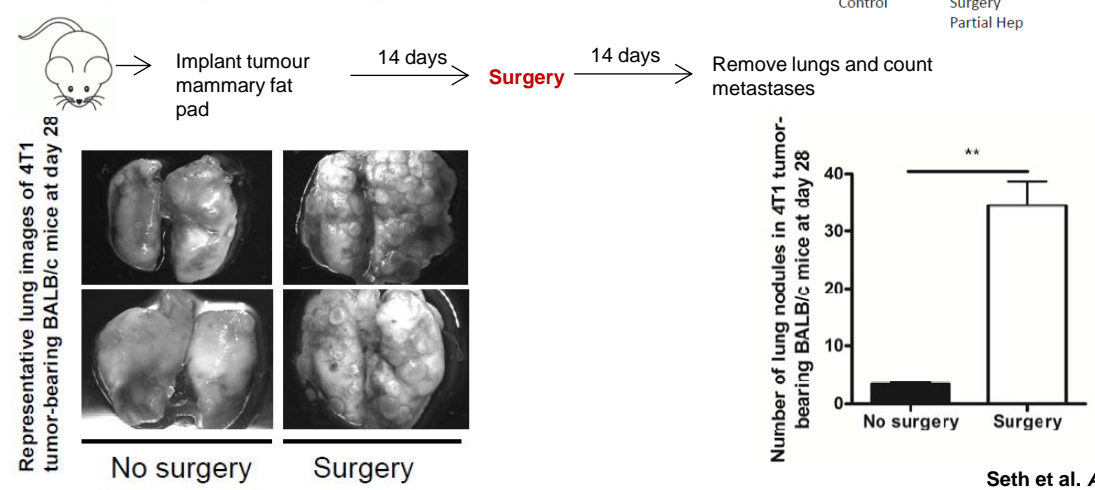
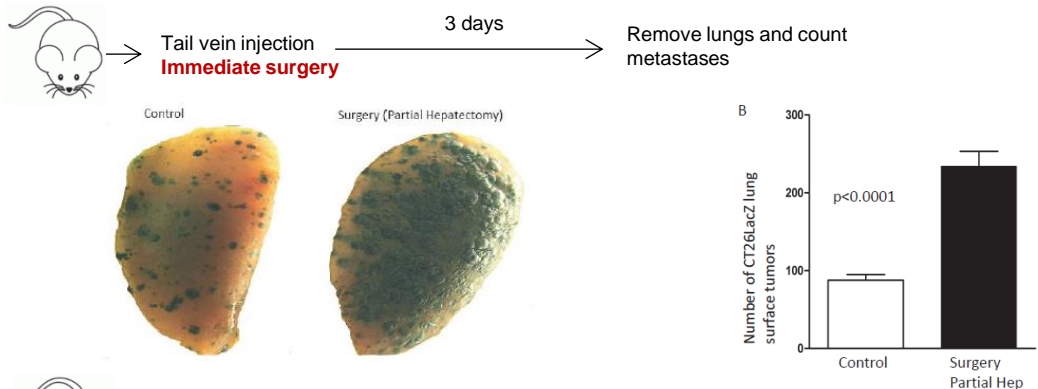


Phases

Cuthbertson. *Lancet* 1942



Auer Lab studies how surgical stress promotes metastases in numerous animal models of metastases



Seth et al. *Annals of Surgery* 2012
 Tai et al. *Cancer Res* 2013

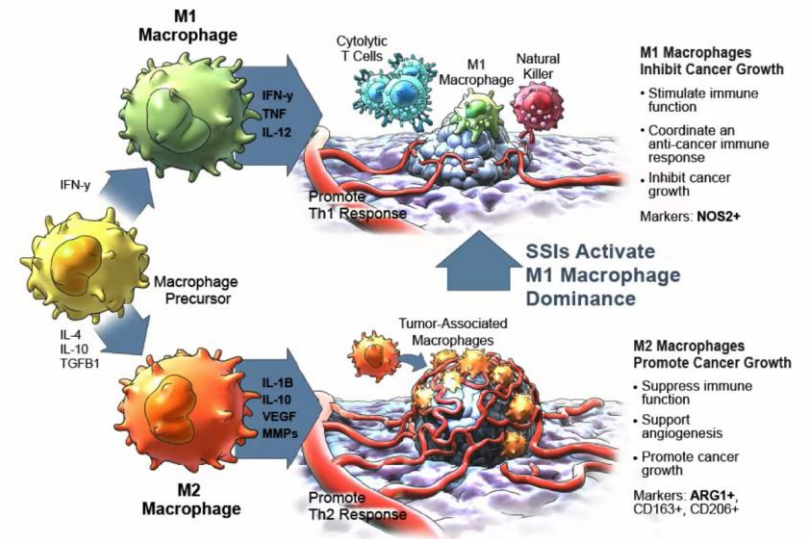


Can innate immune training program postoperative monocytes to be proinflammatory?...PERIOP-06

**SCIENTIFIC
REPORTS**
nature research

Distinct inactivated bacterial-based immune modulators vary in their therapeutic efficacies for treating disease based on the organ site of pathology

Shirin Kalyan^{1,2,5}, Mark Bazett^{1,5}, Ho Pan Sham¹, Momir Bosiljic¹, Beryl Luk¹, Salim Dhanji¹, Amanda M. Costa⁴, Stephanie W. Y. Wong¹, Mihai G. Netea^{1,3}, David W. Mullins^{1,4} & Hal Gunn^{1*}



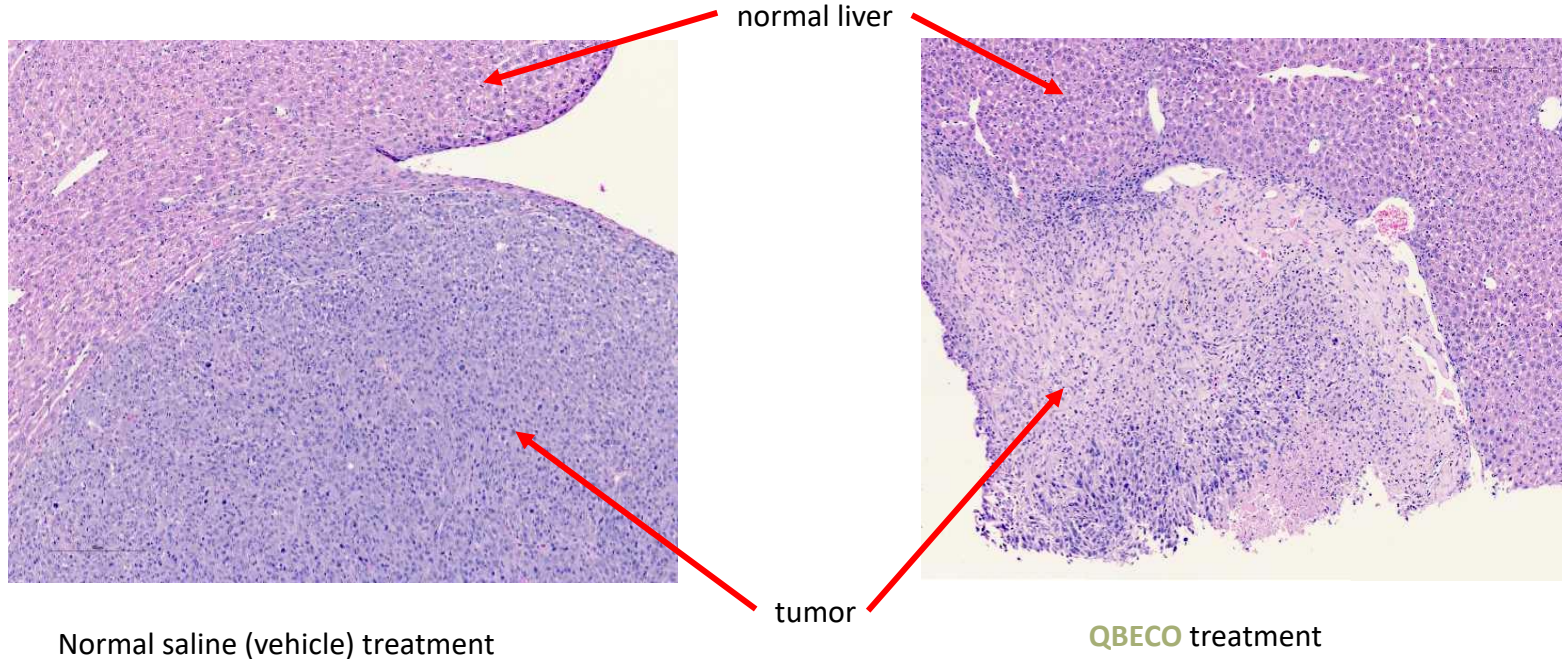
Qubiologics

Netea, M. et al. *Nat Rev Immunol*, 2020

SSI Treatment Induces Tumor Necrosis in Post-Surgical Liver Metastases

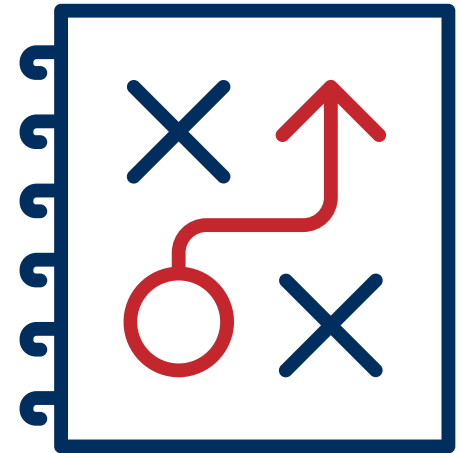
A profound difference was noted histologically between vehicle-treated and QBECO-treated tumors:

- QBECO treatment was associated with areas of **necrosis** and **fibrosis** in the tumor with dead and dying cancer cells.



Design

- **Trial design:** Multicentre, blinded, randomized, placebo-controlled trial
- **Sample size and number of sites:** 115 participants across 5 sites
- **Major eligibility criteria:** Participants must plan to undergo resection of liver lesions for complete clearance of all visible metastatic disease.
- **Intervention:** Participants will be randomized 1:1 to receive QBECO or placebo
- **Outcome:** The primary outcome will be the PFS rate.



Timeline

Recruitment

- Participants will be recruited at each of the participating sites
- Recruitment over the course of 2 years

Device/ Intervention

- QBECO is an SSI formulated from inactivated E. coli bacteria
- Randomized 1:1 to receive either QBECO or placebo via subcutaneous injections

Analysis

- Primary analysis: Intention-to-treat (ITT) cohort for the analysis of the primary and secondary outcomes.
- Correlative analysis: analysis of the correlative outcomes

Updates

- 4 out of 5 sites open to recruitment
- 21 / 115 recruited

