Ectopic pregnancy treatment

Opportunity

About 90 to 95 per cent of ectopic pregnancies that present are stable, where there is no clinical suspicion of rupture. If an efficacious treatment existed these may all be potentially amenable to a medication-based treatment instead of surgery if an efficacious treatment existed.

A medical therapeutic that can resolve ectopic pregnancies of any size could significantly impact on contemporary gynecological care of women.

Background

Ectopic pregnancies are conceptuses implanting outside the uterus, mainly the fallopian tube. They are life-threatening since they may rupture, causing catastrophic and fatal bleeding.

Most are treated surgically. While laparoscopy is safe, important surgical risks remain. Also, the operation usually results in removal of the entire fallopian tube, compromising the women’s fertility.

A medical treatment exists (intramuscular methotrexate), but is only efficacious for small ectopic pregnancies that fulfill strict clinical criteria. Thus, only a minority (around 25 per cent) are small enough to be suitable for methotrexate and most are surgically excised.

Market

All women who present with clinically stable ectopic pregnancies (ie about 95 per cent of ectopics that present).

About two per cent of all pregnancies that present are ectopic. Thus, this equates to 5000 per year in Australia, and 100,000 annually in USA.

Technology

Single injection (methotrexate) and a tablet (EGFR inhibition) to medically cure ectopic pregnancies instead of surgery.

The placenta is critically dependent on the Epidermal Growth Factor Receptor pathway (EGFR) to survive.

Thus, blocking EGFR may be a novel strategy that allows selective targeting of placenta, given placenta has among the highest levels of EGFR expression of any non-malignant tissue in the body.

We have undertaken extensive pre-clinical work robustly demonstrating combination EGFR inhibition and methotrexate (already used to medically treat small ectopics) is supra-additive in potently killing placental tissue.

In these experiments, we used Gefitinib, an orally available small molecule inhibitor that blocks EGFR. Post-marketing surveillance shows it is safe, and remarkably non-toxic.

We have commenced phase I and II clinical trials (Trial number: ACTRN12610000684022), treating women with ectopic pregnancies with combination methotrexate and orally administered Gefitinib. It is centrally coordinated at Monash University, and involves a collaboration with The University of Edinburgh.

Early results suggest very potent responses and prompt cure of ectopics. So far, there have not been notable toxicities.

Advantages

- A single injection (methotrexate) and a short course of tablets to cure ectopic pregnancy
- Avoids surgery, and therefore may be safer
- Easier to administer
- Cheaper
- May preserve fertility
Potential products and applications

Potentially, most ectopic pregnancies that present for medical attention will be suitable for this treatment (we estimate 95 per cent). Only those ectopic pregnancies that where there is suspicion the ectopic has already ruptured will not be suitable (about five per cent or less).

Thus, those who currently have surgery could be treated with this drug combination instead. This will have many important benefits:

- Safer for women, as it avoids surgery and its risks.
- May preserve fertility, as the fallopian tube is not removed.
- Cheaper, where medications replace surgery (theatre set-up, staff, training, surgical equipment).
- Significantly decrease mortality in third world countries, where surgery is the only treatment and is not easily available, resulting in thousands of deaths each year.

Key researchers

Assiciate Professor Stephen Tong

For four years (from 2007 to 2010), Associate Professor Stephen Tong held the Carl Wood Senior Lectureship at Monash University, and was a Senior Scientist at MIMR (Monash Medical Institute of Research). He currently holds an adjunct appointment at The Ritchie Centre at MIMR. He is now based at The University of Melbourne. His research interests relate to the development of therapeutics for ectopic pregnancies, and preeclampsia. He also has an interest in developing novel clinical biomarker tests to identify fetal oxygen starvation.

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Associate Professor Terrance Johns

Associate Professor Terry Johns is currently a senior scientist at MIMR. He heads The Oncogenic Signaling Laboratory. He is an expert in the Epidermal Growth Factor Receptor (EGFR). In previous work at The Ludwig Institute for Cancer Research, he was a key leader in the development of a monoclonal antibody targeting an EGFR variant over-expressed in glioma (a brain tumour). This antibody, mAb 806, is currently undergoing clinical trials. He continues to develop novel therapeutic antibodies designed to treat cancer, with a particular focus on glioma.

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