



TABLET Update October 2011

Trial Description

TABLET is a large double blind placebo controlled trial, to be run in approx. 20 centres in the UK . The purpose of the trial is to test the hypothesis that taking a small (50µg) dose of thyroxine by euthyroid women aged between 16 and 40, with thyroidperoxidase (TPO) antibodies, before and during pregnancy, will increase their chance of delivery beyond 34 weeks of gestation by 10%, compared with the placebo. A systematic review of literature has found that thyroid antibodies are associated with miscarriage and pre-term births.

We will be asking women who have miscarried, and plan to be actively trying to conceive within the next year, to test for thyroid antibodies, via Early Pregnancy Assessment Units (EPAU's). Women who are found to be TPO positive will be asked to consent to be randomised into the trial. We anticipate that we will test 4500 women, and randomise 900 into the trial.

Women will be consented and randomised into the trial via research staff in their own centre, providing that they meet the inclusion/exclusion criteria, and have not previously or currently been treated for a thyroid disease, or taking any excluded medication. 50µg of thyroxine or placebo will be taken daily for up to one year, whilst trying to conceive and throughout the pregnancy. Thyroid function (TSH and T4 levels) will be closely monitored at regular intervals throughout the trial. Women whose thyroid function results fall out of the expected ranges will be withdrawn from the trial, and treated according to standard guidelines.

The necessary Safety Monitoring Procedures have been defined and will be in place in each centre. All participants' General Practitioners will be informed of trial participation.

Following a successful launch meeting in September, recruitment of women for Screening for TPO antibodies began in October 2011 at Birmingham Women's Hospital. Coventry and Warwick Hospital, Ealing Hospital, City and Sandwell Hospital and Crosshouse Hospital Scotland will be recruiting from November, with more centres joining them in December and January.

The TABLET trial is funded by the NIHR Efficacy and Mechanism Evaluation Program, with Professor Arri Coomarasamy as Chief Investigator. We are registered with the NIHR portfolio study number 11051.

The trial is coordinated by Birmingham Clinical Trials Unit ***For more information, please contact Krys Baker on 0121 415 9111 or e-mail k.baker@bham.ac.uk or visit our website at www.tablet.bham.ac.uk***