ISRCTN46178175 https://doi.org/10.1186/ISRCTN46178175

Controlled Antenatal Thyroid Screening study

Submission date	Recruitment status	[_] Prospectively registered
22/07/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/07/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/06/2015	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims.
There is evidence from previous studies that low thyroid function during pregnancy may affect the intelligence quotient (IQ) of the child. However there have been no prospective studies to confirm this. We carried out a study to answer the question: Does testing thyroid function in early pregnancy and treating those women with underactive thyroids improve the IQ of their children?

Who can participate?
We recruited 22000 women pregnant with one baby (singleton pregnancies) before 16 weeks gestation who were not taking thyroid medication.

What does the study involve?
Blood samples were randomly allocated to a screen group and a control group. Thyroid testing was done immediately in all samples from the screen group. The control group samples were stored until the woman delivered the baby and the thyroid test was then carried out. Note: at the time of this trial (2002) there was no routine screening of thyroid function in pregnant women. The screen group women who were found to have an underactive thyroid received Levothyroxine daily for the length of the pregnancy. The control group received no treatment during pregnancy. The women who had an underactive thyroid diagnosed after delivery were referred to their general practitioner for standard care.

What are the possible benefits and risks of participating?
The women participating had a 50% chance of having thyroid function measured during early pregnancy (compared to 0% chance in normal practice). They then had the opportunity to see if the thyroxine intervention improved the IQ of their child compared to the children born to mothers from the control group. Side effects of thyroxine include palpitations and tiredness. Thyroid testing was done in women taking thyroxine 6 weeks after starting and again at 30 weeks of pregnancy. Less than 5% of women required a dose adjustment.

Where is the study run from?
The study was run from the University Hospital of Wales, Cardiff University. There were approximately 8 centres including one in Turin, Italy.

When is the study starting and how long is it expected to run for?
The study started in 2002 and ended in 2010.

Who is funding the study?
Wellcome Trust

Who is the main contact?
Professor JH Lazarus
Lazarus@cf.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof John H Lazarus

Contact details
Cardiff University
University Hospital of Wales
Professor of Clinical Endocrinology/
Heath Park
Cardiff
United Kingdom
CF14 4XN
+44 (0)29 20 742193
Lazarus@cf.ac.uk

Additional identifiers

Protocol serial number
065143

Study information

Scientific Title
Randomised controlled trial of the effect of gestational thyroid hormone intervention therapy on childhood development

Acronym
CATS

Study objectives
Aim is to evaluate strategy of screening of thyroid function in early pregnancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Trent Multi-Centre Research Ethics Committee, 24/06/2004, ref: MREC/04/4/026

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Childhood development

Interventions
Sera obtained from pregnant women before 16 weeks gestation. Sera randomised to 'screen' (T4 and Thyroid Stimulating Hormones [TSH] measured at time of randomisation) and 'control' (hormones measured post delivery) groups. Thyroxine intervention given to screen group with low T4/high TSH and to control group postpartum.
This is the only prospective randomised intervention trial of thyroxine in early pregnancy.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Intelligence Quotient (IQ) of children in screen and control groups.

Key secondary outcome(s))
No secondary outcome measures

Completion date
01/06/2010

Eligibility

Key inclusion criteria
All pregnant women (aged 18 - 45 years) before 16 weeks gestation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Twin pregnancy
2. Thyroid treatment (T4 or antithyroid drugs)

Date of first enrolment
01/06/2002

Date of final enrolment
31/05/2006

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff University
Cardiff
United Kingdom
CF14 4XN

Sponsor information

Organisation
Cardiff University (UK)

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (UK) (grant ref: GRO65143MA)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/02/2012		Yes	No