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Growth Restriction Intervention Trial

Submission date 25/10/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/10/2000	**Overall study status** Completed	
Last Edited 14/07/2014	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G9533539

Study information

Scientific Title

Acronym
GRIT

Study objectives
The aim of this trial is to compare the effect of immediate or delayed delivery for premature fetuses with good evidence of failure to thrive in utero. Cases will be stratified by gestational age and the degree of abnormality of test results. The sole entry criterion will be obstetrician uncertainty about the best management. The primary outcome measure will be Development Quotient at two years of age, with deaths included and scored as zero. The analysis will be stratified by gestation and the degree of test abnormality.

Please note that, as of 14/02/2007, the target number of participants has been updated from 548 to 510 (233 UK; 277 non-UK).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Obstetrics and gynaecology

Interventions
Immediate delivery or defer delivery until uncertainty no longer exists.

Please note that, as of 14/02/2007, the anticipated start and end dates of this trial have been updated to 01/04/1997 and 27/06/2008, respectively.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Development Quotient at two years of age, with deaths included and scored as zero.

Secondary outcome measures
Not provided at time of registration

Overall study start date
09/01/1994

Completion date
31/01/1996

Eligibility

Key inclusion criteria
1. Gestation between 24 - 36 completed weeks
2. Evidence of pregnancy compromise
3. Clinical uncertainty about the optimum timing of delivery. Entry criteria are flexible since the degree of compromise that would make obstetricians consider delivery vary with gestational age and between clinicians

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
510 (233 UK; 277 non-UK)

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
09/01/1994

Date of final enrolment
31/01/1996

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Reproduction, Growth and Development
Leeds
United Kingdom
LS2 9LN

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/01/2003		Yes	No
Results article	results	01/08/2004		Yes	No