ISRCTN98146741 https://doi.org/10.1186/ISRCTN98146741

Leave alone or Induce for the Big BabY

Submission date
21/09/2000

Recruitment status
No longer recruiting

Registration date
21/09/2000

Overall study status
Completed

Last Edited
27/09/2017

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
G0000515

Study information

Scientific Title
Leave alone or Induce for the Big BabY: a randomised controlled trial

Acronym
LIBBY

Study objectives
Does induction of labour for suspected fetal macrosomia confer maternal or fetal benefits?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Pilot study for randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Suspected fetal macrosomia

Interventions
Not provided at time of registration.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Fetal birth trauma (Erbs palsy or any fracture, or neonatal convulsions or intra-cerebral haemorrhage or need for admission to intensive care
2. Instrumental vaginal delivery
3. Caesarean section
4. Maternal injury

Secondary outcome measures
Not provided at time of registration.

Overall study start date
26/07/1999

Completion date
18/02/2003

Eligibility

Key inclusion criteria
Not provided at time of registration.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
72 in each group (total = 144)

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
26/07/1999

Date of final enrolment
18/02/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Obstetrics and Gynaecology
Nottingham
United Kingdom
NG7 2RD

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
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
Added 27/09/17: This was a pilot study. The results were given to the Cochrane reviewers and included in the relevant Cochrane Review (see publication summary section). No other publication plans.

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	pilot results within Cochrane Review	01/08/2000		Yes	No