

Leave alone or Induce for the Big BabY

Submission date 21/09/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/09/2000	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/09/2017	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr James G Thornton

Contact details
Department of Obstetrics and Gynaecology
The University of Nottingham University Park
Nottingham
United Kingdom
NG7 2RD

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration.

Completion date

18/02/2003

Eligibility**Key inclusion criteria**

Not provided at time of registration.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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**

United Kingdom

England

Study participating centre

Department of Obstetrics and Gynaecology

Nottingham

United Kingdom

NG7 2RD

Sponsor information**Organisation**

Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

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