

Does feeding during labour influence the outcome?

Submission date 09/12/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 17/12/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/03/2009	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Does feeding during labour influence the outcome?: a randomised controlled trial

Acronym

FIL

Study objectives

Light diet in labour increases the chances of spontaneous vaginal delivery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

St Thomas' NHS Ethics Committee, approved on 11/10/2000 (ref: EC99/135)

Study design

Randomised controlled multi-centre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Health condition(s) or problem(s) studied

Labour/delivery

Interventions

Light diet versus water and ice chips. Suggested foods include bread, biscuits, vegetables, fruits, low-fat yoghurt, soup, isotonic drinks and fruit juice.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Spontaneous vaginal delivery.

Secondary outcome measures

1. Instrumental vaginal and caesarean section deliveries
2. Need for augmentation
3. Vomiting
4. Neonatal outcomes:
 - 4.1. Apgar scores
 - 4.2. Admission to neonatal intensive care unit (NICU)/ special care baby unit (SCBU)

Overall study start date

01/06/2001

Completion date

01/04/2006

Eligibility

Key inclusion criteria

1. Females, no age limits
2. Primiparous women >36 weeks gestation
3. Singleton pregnancies
4. No maternal or foetal complications
5. Cervical dilatation less than or equal to 5 cm

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

1,126

Key exclusion criteria

1. Multiparous women
2. <36 weeks' gestation
3. Known maternal or foetal complication
4. Cervical dilatation >5 cm

Date of first enrolment

01/06/2001

Date of final enrolment

01/04/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Maternal and Foetal Research Unit
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
King's College London (UK)

Sponsor details
Conybeare House
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Sponsor type
University/education

Website
<http://www.kcl.ac.uk>

ROR
<https://ror.org/0220mzb33>

Funder(s)

Funder type
Charity

Funder Name
Obstetric Anaesthetists Association (UK)

Alternative Name(s)

OAA

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Funder Name

Guy's and St Thomas' (GSTT) charity (UK)

Alternative Name(s)

Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

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	24/03/2009		Yes	No