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Hospital discharge on the first versus second day after planned cesarean delivery

Submission date
29/05/2012

Recruitment status
No longer recruiting

Registration date
06/06/2012

Overall study status
Completed

Last Edited
30/11/2015

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
The Caesarean delivery rate is steadily increasing and now accounts for 20-30% of deliveries in many developed countries. There has been a steady decline in the length of time mothers spend in hospital after giving birth including after Caesarean delivery. Earlier discharge may give more opportunity for family members to be together as they get to know the baby, contributing to improved bonding, more involvement of the father in caring for the baby and decreased exposure of the mother and baby to hospital-acquired infection. However, earlier discharge may cause a delay in treatment if unsuspected complications were to arise. We are doing a study to compare discharge on Day 1 (next day) versus Day 2 (current standard) after an uncomplicated elective Caesarean delivery in healthy women who have made a good physical recovery and whose baby is also fit for discharge.

Who can participate?
Healthy women aged 18 and above, at term with a singleton pregnancy, admitted for a planned Caesarean delivery.

What does the study involve?
Participants are assessed on the day after the Caesarean to see whether they have recovered sufficiently to be considered for Day 1 discharge. If the mother and baby are considered fit, they are randomly allocated to be discharged either on Day 1 or Day 2. If they are not fit for discharge, they are discharged only when they are ready with standard follow-up to come. Participants attend follow up appointments after 2 and 6 weeks where they receive routine medical assessment and complete questionnaires. If they are not able to come for the follow-ups, we call them by telephone to get their responses to the questionnaires.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Antenatal and postnatal wards, University Malaya Medical Centre, Kuala Lumpur, Malaysia.

When is the study starting and how long is it expected to run for?
November 2010 to April 2012

Who is funding the study?
Department of Obstetrics and Gynaecology, University Malaya Medical Centre, Malaysia.

Who is the main contact?
Prof P C Tan

Contact information

Type(s)
Scientific

Contact name
Prof Peng Chiong Tan

Contact details
Department of Obstetrics & Gynaecology
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Malaysia
50603

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
811.7

Study information

Scientific Title
Hospital discharge on the first versus second day after planned cesarean delivery: a randomized trial

Study objectives
Post caesarean Day 1 (next day) compared to Day 2 discharge will result in equivalent patient satisfaction and exclusive breastfeeding rates at 6 weeks.

Ethics approval required
Old ethics approval format

Ethics approval(s)

University of Malaya Medical Centre Medical Ethics Committee, 22/09/2010, ref: 811.7

Study design
Randomized trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Caesarean delivery

Interventions
Hospital discharge after planned caesarean delivery: Day 1 (next day) or Day 2

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Patient satisfaction with allocated hospital discharge protocol assessed 2 weeks after discharge (5-point Likert scale)
2. Self reported exclusive breastfeeding at 6 weeks

Secondary outcome measures
At 2 weeks:
1. Satisfaction with discharge protocol based on the full 5-point Likert scale
2. General well being score using a 10 point numerical rating scale (NRS)
3. Recommendation of their timing of discharge after cesarean to a friend (5-point Likert scale)
4. Preferred length of hospital stay after cesarean
5. Infant feeding status
6. Baby unscheduled medical consultation
7. Maternal antibiotic
8. Cesarean wound condition

At 6 weeks:
1. General well being score [Numerical rating scale (NRS)]

2. Maternal unscheduled medical consultation
3. Baby unscheduled medical consultation
4. Maternal antibiotic
5. Cesarean wound condition
6. Assessment of maternal anxiety and depression using the Hospital Anxiety and Depression scale

Overall study start date
05/11/2010

Completion date
15/04/2012

Eligibility

Key inclusion criteria
1. Planned cesarean delivery
2. Age ≥ 18 years
3. Gestation ≥ 37 weeks
4. A singleton pregnancy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
360

Key exclusion criteria
1. ≥ 2 previous Cesarean
2. Major praevia
3. Grossly fetal anomaly
4. Pre eclampsia
5. Established medical disorders (e.g. pregestational diabetes, epilepsy, cardiac disease, renal disease, connective tissues disease, anti-phospholipid syndrome)

Date of first enrolment
05/11/2010

Date of final enrolment
15/04/2012

Locations

Countries of recruitment
Malaysia

Study participating centre
University of Malaya
Kuala Lumpur
Malaysia
50603

Sponsor information

Organisation
University of Malaya (Malaysia)

Sponsor details
Department of Obstetrics and Gynaecology
Faculty of Medicine
Lembah Pantai
Kuala Lumpur
Malaysia
50603

Sponsor type
University/education

Website
http://medicine.um.edu.my/?modul=DEPARTMENTS&pilihan=Obstetrics_and_Gynecology

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
University/education

Funder Name
University of Malaya (Malaysia)

Alternative Name(s)

University of Malaya, University Malaya, Malayan University, UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

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	01/12/2012		Yes	No
Results article	results	01/12/2012		Yes	No