

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

Submission date 29/05/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/06/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 30/11/2015	Condition category Pregnancy and Childbirth	<input type="checkbox"/> 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

Faculty of Medicine

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50603

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

15/04/2012

Eligibility

Key inclusion criteria

1. Planned cesarean delivery
2. Age \geq 18 years
3. Gestation \geq 37 weeks
4. A singleton pregnancy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. \geq 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)

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, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Malaysia

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary****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