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Lacking capacity to consent in emergencies related to child birth

Submission date
06/10/2016

Recruitment status
No longer recruiting

Registration date
06/12/2016

Overall study status
Completed

Last Edited
06/12/2021

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

This research is in 2 phases.

Phase1: Lacking capacity in an obstetric emergency, a retrospective study of maternal capacity.
Phase2: Lacking capacity in an obstetric emergency, a randomized controlled trial investigating whether prior information about obstetric emergencies improves later decision making capacity.

The Mental Capacity Act (MCA) 2005 was introduced to protect patients' autonomy and to provide for those lacking capacity. It has significant implications for consent in obstetric emergencies.

Due to the nature of obstetric emergencies, informed consent is challenging. Fear of fetal well-being, severe labour pains, strong opiates and emotional (dis)stress all affect capacity. Formal assessment of capacity takes considerable time, which may compromise fetal outcome through undue delay.

We recently conducted an audit and found that the majority of women interviewed within 24 hrs of an obstetric emergency, had no recollection of the consent process or risks of complications. Many admitted to not reading the consent form at all.

In phase1, we assess a mother's ability to give informed consent in an emergency by conducting interviews within 24 hrs of birth, using a capacity assessment tool designed by us that incorporates basic principles of the MCA, based upon maternal recall of events.

In phase2: we are testing whether written information, supported by verbal counselling, before an emergency has occurred improves women's decision making ability when an emergency occurs subsequently.

Women admitted for induction of labour or early labour will be randomized to receive additional information (intervention) or not (control). Those women who end up in theatre for an instrumental or caesarean delivery will be interviewed within 24 hrs to assess their capacity at the time of emergency.
Usual practice is to take consent when an emergency arises.

This study will be conducted at Glan Clwyd Hospital and will last approximately 12 months. BCUHB will be the sponsor.

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number
183899

ClinicalTrials.gov number

Secondary identifying numbers
IRAS 183899

Study information

Scientific Title
Lacking Capacity in Obstetric Emergencies

Study objectives
A timely intervention in the form of written information supported with verbal counselling improves women's decision making ability.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 4, 27/11/2015, ref: 15/WA/0273

Study design
Phase 1: Observational cross-sectional retrospective case assessment
Phase 2: Randomised controlled 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
Women's health

Interventions
All women who have been to theatre for an obstetric emergency delivery (code 1 or code 2) are assessed and interviewed using the R-CAT tool to assess their capacity in retrospect. This is done ideally as soon as possible and within 24 hours after the emergency event had happened.
The R-CAT tool involves reviewing patient notes for details about the delivery (such as reason for going to theatre, urgency, and use of pain relief) and an interview with the patient. The interview takes approximately 40 minutes to complete and involves asking questions about the events around the delivery to find out what patient can recall and what she understood at that time.

Phase 2:
Women will be randomized to one of two groups using the online system of randomization facilitated by the R&D department of BCUHB.

Control group: Women will be treated in the routine manner as per national guidelines with no additional information or intervention and if she ends up in theatre for emergency delivery, then will be approached by the research team to make and assessment of her capacity in retrospect,

using our specially designed R-CAT tool which combines the principles of Mental Capacity Act 2005 with McArthur's capacity assessment tool. This assessment will be done within 24 hours of delivery.

Intervention group: Women will receive written information with verbal counselling regarding the possible obstetric emergency procedures. If she continues to deliver normally and does not need to go to theatre, nothing needs to be done, however if she does need to go to theatre as an Obstetric emergency and have delivery in theatre, This patient post delivery will be assessed by using the R-CAT tool to make a retrospective assessment of her capacity at the point she was taken to theatre. This assessment is done as soon as possible after the delivery but within 24 hours of patient having been to theatre.

All participants are interviewed within 24 hours of delivery, otherwise there is no other follow up.

Intervention Type
Other

Primary outcome measure
Phase 1 and 2:
Capacity is measured using the R CAT tool within 24 hours of delivery.

Secondary outcome measures
No secondary outcome measures

Overall study start date
31/12/2015

Completion date
01/09/2017

Eligibility

Key inclusion criteria
Phase 1:
1. Aged 16 years and over
2. Singleton live pregnancy
3. ≥ 36 weeks pregnancy
4. Those who have been to theatre for an obstetric emergency delivery

Phase 2
1. All women admitted for induction of labour or in very early labour judged not to be under the influence of opiate analgesia
2. Aged 16 years and over
3. Singleton live pregnancy
4. ≥ 36 weeks pregnancy

Participant type(s)
Patient

Age group

Adult

Lower age limit
16 Years

Sex
Female

Target number of participants
Phase 1: The sample size will be based on a pilot study that preceded this application such that 90 participants will be recruited to assess their capacity in retrospect after the event. Phase2: 250 control Group and 250 intervention Group.

Key exclusion criteria
Phase 1 and 2:
1. Under 16 years of age
2. Learning disability
3. Organic mental disorders
4. In significant pain or under the influence of opiate analgesia

Date of first enrolment
01/01/2016

Date of final enrolment
01/08/2017

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Glan Clwyd Hospital
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Sponsor information

Organisation

Betsi Cadwaladr University Health Board

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Sponsor type
Research organisation

ROR
https://ror.org/03awsb125

Funder(s)

Funder type
Research organisation

Funder Name
Betsi Cadwaladr University Health Board

Results and Publications

Publication and dissemination plan
Planned publication in the BJOG (British Journal of Obstetrics & Gynaecology).

Intention to publish date
01/09/2018

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article		29/01/2021	06/12/2021	Yes	No
HRA research summary			28/06/2023	No	No