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Video information to support the process of obtaining informed consent: using foetal tissue for brain tumour research

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 21/01/2009	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

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
N0192107555

Study information

Scientific Title
A randomised controlled trial of the use of video information to support the process of obtaining informed consent: to use foetal tissue for brain tumour research

Study objectives
To assess whether the use of recorded media (video tape) within the informed consent process is as acceptable, feasible and informative as the conventional face-to-face informed consent processes used in current clinical practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Informed consent processes

Interventions
Randomised controlled trial to assess whether the use of recorded media (video tape) within the informed consent process is as acceptable, feasible and informative as the conventional face-to-face informed consent processes used in current clinical practice.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Patient assessment of acceptability
2. Patient anxiety levels
3. Patient level of relevant knowledge
4. Patient degree of satisfaction
5. Clinical feasibility and acceptability of the different methods of obtaining informed consent

Secondary outcome measures
Not provided at time of registration

Overall study start date
30/01/2002

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Age range of subjects 18 - 40 years
2. Female

Participant type(s)
Patient

Age group
Neonate

Sex
Female

Target number of participants
Patients = 20 terminations of pregnancy

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
30/01/2002

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Division of Child Health
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Queen's Medical Centre University Hospital NHS Trust (UK)

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?
Interim results article	interim results	01/12/2003		Yes	No