

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 21/01/2009	Condition category Other	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number

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

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2006

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

Female

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

United Kingdom

England

Study participating centre

Academic Division of Child Health

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

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