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Effect of intravenous (IV) sedation on patient satisfaction after cataract surgery with topical anaesthesia

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 31/03/2020	**Condition category** Surgery	

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
N0141125451

Study information

Scientific Title
Effect of intravenous (IV) sedation on patient satisfaction after cataract surgery with topical anaesthesia

Study objectives
To determine the effect of IV midazolam on patient satisfaction after cataract surgery with topical anaesthesia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective randomised single masked pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Cataract

Interventions
Randomised to sedation or placebo

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Midazolam

Primary outcome measure

Patient satisfaction

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2003

Completion date
31/07/2003

Eligibility

Key inclusion criteria
30 patients for cataract surgery

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
15 for sedation, 15 for placebo

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/04/2003

Date of final enrolment
31/07/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Moorfields Eye Hospital
London
United Kingdom
EC1V 2PD

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
Hospital/treatment centre

Funder Name
Moorfields Eye 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