ISRCTN34193340 https://doi.org/10.1186/ISRCTN34193340

Comparative study of local anaesthesia, forced coughing and no anaesthesia for pain reduction in colposcopically directed cervical punch biopsies

Submission date 08/06/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 09/07/2009	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 24/11/2009	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Mehmet Murat Naki

Contact details
Cihat Saran Sk. Cagdas Apt. No:11/3
Kucukyali Maltepe
Istanbul
Türkiye
34841
mmuratnaki@yahoo.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Comparative study of local anaesthesia, forced coughing and no anaesthesia for pain reduction in colposcopically directed cervical punch biopsies: a randomised trial

Study objectives
Is there any differences between local anaesthesia, forced coughing and no local anaesthesia for pain reduction in cervical punch biopsies?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Dr. Lutfi Kirdar Kartal Research and Training Hospital approved on the 26th March 2009 (ref: 18/28.05.2009)

Study design
Randomised controlled single centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Abnormal pap smear/cervical punch biopsy

Interventions
Please note that as of 24/11/09, the end date of this trial had been extended from 01/09/09 to 01/12/09.

This trial is taking place at the Istanbul Dr. Lutfi Kirdar Kartal Research and Training Hospital, Department of Obstetrics and Gynaecology. Approximately 114 patients will be recruited, 38 patients in each of the following three groups:

1. Local anaesthesia with lidocaine
2. Forced coughing
3. No local anaesthesia

Patient allocation will be carried out as follows:
A computer based randomisation will be prepared. The anaesthesia type will be printed on identical sheets of paper, which will be put into identical, consecutively numbered sealed opaque envelopes by a non-participating colleague.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Pain score when the first biopsy performed

Secondary outcome measures
Pain score for overall procedure

Overall study start date
01/06/2009

Completion date
01/12/2009

Eligibility

Key inclusion criteria
1. Women between ages of 18 - 65 years
2. Abnormal pap smears indicated cervical punch biopsy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Female

Target number of participants
Approximately 114

Key exclusion criteria
1. Any contraindications for parenteral analgesics
2. Any contraindications for lidocaine
3. Pregnancy

Date of first enrolment
01/06/2009

Date of final enrolment
01/12/2009

Locations

Countries of recruitment
Türkiye

Study participating centre
Cihat Saran Sk. Cagdas Apt. No:11/3
Istanbul
Türkiye
34841

Sponsor information

Organisation
Dr. Lutfi Kirdar Kartal Research and Training Hospital (Turkey)

Sponsor details
c/o M. Murat Naki
Department of Obstetrics and Gynaecology
Istanbul
Türkiye
34841

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01c2wzp81

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Dr. Lutfi Kirdar Kartal Research and Training Hospital (Turkey) - Department of Obstetrics and Gynaecology

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