

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

|  |   |  |
|--|---|--|
| <b>Submission date</b><br>08/06/2009   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>09/07/2009 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>24/11/2009       | <b>Condition category</b><br>Surgery              | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input type="checkbox"/> Results                     |
|  |   | <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

### 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

### Protocol serial number

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

**Study type(s)**

Treatment

**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(s)**

Pain score when the first biopsy performed

**Key secondary outcome(s)**

Pain score for overall procedure

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

65 years

**Sex**

Female

**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)

### 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

### 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? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |