

# Comparison of effects of LigaSure™ with those of Monopolar Electrocautery on wound healing in early post-operative period after pilonidal sinus surgery

<b>Submission date</b> 24/10/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 08/11/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/10/2011	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

Project no.: 10-03-16-40

# Study information

## Scientific Title

Comparison of effects of LigaSure™ with those of Monopolar Electrocautery on wound healing in early post-operative period after pilonidal sinus surgery: a prospective randomised controlled clinical trial

## Acronym

LSME

## Study objectives

To investigate effects of LigaSure™ with monopolar electrocautery on wound healing in the early post-operative period after pilonidal sinus surgery.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Eskişehir Osmangazi University Research Council and Local Ethics Committee approved on the 21st May 2010 (ref: 10-03-16-40)

## Study design

Prospective randomised controlled clinical 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

Sacroccygeal pilonidal disease

## Interventions

Following an incision in the skin, pilonidal sinus excision was performed with monopolar electrocautery in the control group (n = 64) (Group ME) and with LigaSure™ in the study group (n = 64) (Group LS). Demographic variables, history, physical examination findings, defect dimensions and scores for Visual Analogue Scale (VAS) and patient satisfaction were recorded.

After collecting the adequate number of subjects at least 3 months of follow-up and for recovery till the wound healing. Nearly 1 year total duration of treatment.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Surgical site infections, assessed based on the hospital infection control practices advisory committee guidelines
2. Early wound failure (dehiscence), considered as breakdown and dehiscence of the sutured wound with or without infection
3. Recurrence

**Secondary outcome measures**

1. Post-operative use of antibiotics
2. Time to remove sutures
3. Time to wound healing (days), refers to full epithelisation over the wound. When the wound was not healed in the month after surgery, the follow-up of the wound was continued until the wound healed completely.
4. Time to return to all daily activities
5. Time to complete recovery, defined as return to all activities and as complete healing of the wound
6. Patient satisfaction
7. Pain

**Overall study start date**

01/12/2009

**Completion date**

30/08/2010

**Eligibility****Key inclusion criteria**

1. Consecutive patients aged greater than 18 years, either sex
2. Pilonidal disease
3. Considered appropriate for primary closure
4. Giving informed consent

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

128

**Key exclusion criteria**

1. Declining to participate in the study
2. Having prior surgery for the disease
3. Found to have abscess and infection

**Date of first enrolment**

01/12/2009

**Date of final enrolment**

30/08/2010

## **Locations**

**Countries of recruitment**

Türkiye

**Study participating centre**

Adana Teaching and Research Center

Adana

Türkiye

01250

## **Sponsor information**

**Organisation**

Başkent University (Turkey)

**Sponsor details**

Dadaloglu mah. 39. sok

No:6 Yuregir

Adana

Türkiye

01250

**Sponsor type**

University/education

**Website**

<http://www.baskent.edu.tr/>

**ROR**

<https://ror.org/02v9bqx10>

## Funder(s)

**Funder type**

Other

**Funder Name**

Investigator initiated and funded (Turkey)

## 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?
<a href="#">Results article</a>	results	01/09/2011		Yes	No