

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

Submission date 24/10/2010	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 08/11/2010	Overall study status Completed	☐ Protocol
Last Edited 26/10/2011	Condition category Skin and Connective Tissue Diseases	☐ Statistical analysis plan
		☒ Results
		☐ 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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Additional identifiers

Protocol serial number

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)

Primary study design

Interventional

Study design

Prospective randomised controlled clinical trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

ROR

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

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (Turkey)

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?
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[Results article](#)

results

01/09/2011

Yes

No