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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

Registration date
08/11/2010

Overall study status
Completed

Last Edited
26/10/2011

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
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)
Eski°ehir 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
Sacrococcygeal 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?
Results article	results	01/09/2011		Yes	No