

Lymph nodal dissection of the groin in skin malignant melanoma surgery - does the dissection technique have an impact on wound healing: scalpel versus ultrasonic assisted versus electrocauter

Submission date 25/07/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/12/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/12/2008	Condition category Surgery	<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

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Additional identifiers

Protocol serial number
FKH-PCH-2008-1

Study information

Scientific Title

Study objectives

Lymph nodal dissection of the groin for melanoma of the skin is known as a high wound complication procedure. The surgical procedure has been described very similarly for decades. For the tissue dissection there are different well-experienced techniques. These are the traditional scalpel dissection, the ultrasonic assisted and the electrocauter assisted dissection technique. All equipment is CE certified and use is currently up to the surgeons referrals.

Evidence based decision making should be standard in todays medical treatment. In surgery evidence-based data is very rare. Concerning the described question for the impact of the dissection technique for the groin dissection there is no data available. Wound healing is a major problem in this group of patients. In medical literature a complication rate up to almost 50% (wound infection, healing problems, seroma, lymph fistula, lymphoedema, etc.) is being reported.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval pending from the Ethikkommission der Ärztekammer Westfalen Lippe as of 28 /07/2008.

Study design

Prospective, randomised, double blind, monocentric trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Wound healing in skin malignoma surgery

Interventions

The surgical procedure is the same for all the patients. There will be three groups for the different tissue dissection techniques:

1. Dissection with the scalpel/scissors
2. Ultrasonic assisted dissection
3. Electrocautery assisted dissection

The follow-up will be 3 months in all arms.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

Length of hospital stay (days), evaluated at the time of hospital discharge of the patient

Key secondary outcome(s)

1. Amount of wound drainage (ml), evaluated at the time of hospital discharge of the patient
2. Time of drainage in situ (days), evaluated at the time of hospital discharge of the patient
3. Cost of treatment (Euro), evaluated after the 3 month follow-up

Completion date

30/04/2011

Eligibility

Key inclusion criteria

1. Indication for a lymph nodal dissection of the groin for a skin malignant melanoma
2. Aged over 18 years, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Non-consent
2. Aged under 18 years
3. Mentally disabled

Date of first enrolment

01/09/2008

Date of final enrolment

30/04/2011

Locations

Countries of recruitment

Germany

Study participating centre
Leitender Arzt
Münster
Germany
48157

Sponsor information

Organisation
Ethicon Endo-Surgery (Germany)

ROR
<https://ror.org/023edjq13>

Funder(s)

Funder type
Industry

Funder Name
Ethicon Endo-Surgery (Germany) - received funding only; the study was independently performed and initiated by the hospital department

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes