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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	[_] Prospectively registered [_] Protocol
Registration date 17/12/2008	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 17/12/2008	**Condition category** Surgery	[_] Individual participant data [_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Ärtzekammer Westfalen Lippe as of 28 /07/2008.

Study design
Prospective, randomised, double blind, monocentric 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

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

Secondary outcome measures
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

Overall study start date
01/09/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

120 (40 patients per group)

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
Leitdender Arzt
Münster
Germany
48157

Sponsor information

Organisation
Ethicon Endo-Surgery (Germany)

Sponsor details
Hummelsbütteler Steindamm 71
Norderstedt
Gibraltar
22851

Sponsor type
Industry

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

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