Classical versus Modern Local Wound Care in Surgical Patients: A Randomized Controlled Trial

Submission date	Recruitment status	Prospectively registered		
04/01/2006	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
05/01/2006	Completed	[X] Results		
Last Edited 11/01/2021	Condition category	[] Individual participant data		
11/01/2021	Skin and Connective Tissue Diseases			

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

IBC15010, NL492, NTR534

Study information

Scientific Title

Classical versus Modern Local Wound Care in Surgical Patients: A Randomized Controlled Trial

Acronym

MOKUM trial

Study objectives

Occlusive, non-gauze based wound dressings are more effective (as to time to complete wound healing, pain during dressing changes, and costs) than non-occlusive, gauze-based dressings for local wound care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Wound Care

Interventions

Occlusive wound dressing materials versus gauze dressings

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Time to complete wound healing

Secondary outcome measures

- 1. Pain during dressing changes
- 2. Material and nursing costs of dressing changes
- 3. Duration of hospitalisation
- 4. Adverse effects of dressings

Overall study start date

23/04/2004

Completion date

14/09/2005

Eligibility

Key inclusion criteria

- 1. Adult patients admitted to the departments of surgery with open wounds requiring local wound care
- 2. Written informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

285

Total final enrolment

285

Key exclusion criteria

- 1. Burn and malignant wounds
- 2. Surgically closed wounds
- 3. Wounds treated with vacuum assisted closure (VAC) devices
- 4. Ostomies or drain openings
- 5. Pin holes from external fixation materials
- 6. Patients receiving chemotherapy or local irradiation therapy
- 7. Patients with a life expectancy <6 months

Date of first enrolment

23/04/2004

Date of final enrolment

14/09/2005

Locations

Countries of recruitment

Netherlands

Study participating centre
Academic Medical Center (AMC), Department of Surgery
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation

Academic Medical Center (AMC), Department of Surgery (The Netherlands)

Sponsor details

Postbus 22660 Amsterdam Netherlands 1105 AZ

Sponsor type

University/education

ROR

https://ror.org/03t4gr691

Funder(s)

Funder type

Industry

Funder Name

M, Smith&Nephew, Johnson & Johnson, Convatec

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	01/10/2008	11/01/2021	Yes	No