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Fluid Lavage of Open Wounds (FLOW)

Submission date	Recruitment status	[_] Prospectively registered
09/07/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/07/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/04/2019	Injury, Occupational Diseases, Poisoning	

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
NCT00788398

Secondary identifying numbers
MCT-93173; FLOW-01

Study information

Scientific Title

Fluid Lavage of Open Wounds (FLOW): a multicentre, blinded, factorial trial comparing alternative irrigating solutions and pressures in patients with open fractures

Acronym
FLOW

Study objectives
1. In patients operatively treated for open fractures of the extremity, irrigation with soap will result in lower rates of re-operations within one year after initial surgery as compared to saline
2. In patients operatively treated for open fractures of the extremity, irrigation at low pressure will result in lower rates of re-operations within one year after initial surgery as compared to high pressure

Ethics approval required
Old ethics approval format

Ethics approval(s)
McMaster Faculty of Health Sciences/Hamilton Health Sciences Research Ethics Board approved on the 2nd September 2008 (ref: 08-268)

Study design
Multicentre blinded randomised controlled trial, using a 2 x 3 factorial design

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
Open fracture wounds

Interventions
Irrigation of open fracture wound with one of the following:
1. Saline solution delivered at gravity pressure (1 - 2 psi)
2. Saline solution delivered with an irrigator at low pressure (5 - 10 psi)
3. Saline solution delivered with an irrigator at high pressure (greater than 20 psi)
4. Castile soap solution (80 ml per 3 litres saline) delivered at gravity pressure (1 - 2 psi)
5. Castile soap solution (80 ml per 3 litres saline) delivered with an irrigator at low pressure (5 - 10 psi)

6. Castile soap solution (80 ml per 3 litres saline) delivered with an irrigator at high pressure (greater than 20 psi)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Re-operation within 12 months post-initial surgery to treat an infection, manage a wound healing problem, or promote fracture healing.

Secondary outcome measures
Patient function and quality of life measured by the 12-item Short Form (SF-12) and the EuroQol-5D, assessed at 1 week, 2 weeks, 6 weeks, 3 months, 6 months, 9 months and 12 months.

Overall study start date
01/06/2009

Completion date
01/01/2012

Eligibility

Key inclusion criteria
1. Men or women who are 18 years of age or older
2. Fracture of any extremity with complete radiographs
3. Open fractures (Gustilo-Anderson Types I-IIIB)
4. Fracture requiring operative fixation
5. Provision of informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2280

Key exclusion criteria
1. Open fractures with an associated vascular deficit (Gustilo-Anderson Type IIIC)
2. Known allergy to detergents or castile soap ingredients

3. Previous wound infection or history of osteomyelitis in the injured extremity
4. Previous fracture with retained hardware in injured extremity that will interfere with new implant fixation
5. Surgical delay to operative wound management greater than 24 hours from hospital admission
6. Use of immunosuppressive medication within 6 months
7. Immunological deficient disease conditions (e.g., human immunodeficiency virus [HIV])
8. Fracture of the hand (metacarpals and phalanges)
9. Fracture of the toes (phalanges)
10. Likely problems, in the judgment of the investigators, with maintaining follow-up. We will, for example, exclude patients with no fixed address, those who report a plan to move out of town in the next year, or intellectually challenged patients without adequate family support.
11. Previous randomisation in this study or a competing study
12. Patient is a prisoner or is at high risk of incarceration during the follow-up period

Date of first enrolment
01/06/2009

Date of final enrolment
01/01/2012

Locations

Countries of recruitment
Australia

Canada

United States of America

Study participating centre
293 Wellington Street North, Suite 110
Hamilton, Ontario
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Sponsor information

Organisation
McMaster University (Canada)

Sponsor details
CLARITY Research Group
293 Wellington Street North, Suite 110
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Sponsor type
University/education

Website
http://www.mcmaster.ca/

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-93173)

Funder Name
United States Department of Defense (USA) (Proposal Log No.: 07128039)

Funder Name
International Association for Dynamic Osteosynthesis (Association Internationale pour l'Ostéosynthèse Dynamique [AIOD]) (France) - Research Grant (ref: 080407-MBES)

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?

Protocol article	protocol results	06/05/2010	10/04/2019	Yes	No
Results article	results	31/12/2015	10/04/2019	Yes	No
Results article	results	01/01/2019	10/04/2019	Yes	No