

Fluid Lavage of Open Wounds (FLOW)

Submission date 09/07/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 13/07/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 10/04/2019	Condition category Injury, Occupational Diseases, Poisoning	☐ 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

ClinicalTrials.gov (NCT)
NCT00788398

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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-III B)
4. Fracture requiring operative fixation
5. Provision of informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Canada

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Sponsor information

Organisation

McMaster University (Canada)

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

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