Prospective Abuse and Intimate Partner Violence Surgical Evaluation (PRAISE-2) Protocol

Published: 18-04-2017
Last updated: 14-04-2024

The primary objectives are to determine the feasibility of a multi-national prospective cohort study:1) Assess our ability to recruit women across clinical sites and compare actual recruitment rates to our current estimates;2) Evaluate adherence to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Observational non invasive

Summary

ID

NL-OMON43260

Source
ToetsingOnline

Brief title
PRAISE-2

Condition

- Fractures

Synonym
Musculoskeletal injury

Research involving
Human

Sponsors and support

Primary sponsor: McMaster University
Source(s) of monetary or material Support: McMaster University

Intervention

Keyword: Intimate partner violence, Musculoskeletal injury

Outcome measures

Primary outcome

The primary outcome of the pilot study will be a composite measure of feasibility. This will include:

1) Recruitment (number of patients recruited at each site during a 12 month period)

2) Protocol adherence (application of eligibility criteria)

3) Follow-up (proportion of included patients followed at 12 months)

4) Data quality (the proportion of case report forms, including patient questionnaires completed at 12 months)

Secondary outcome

Secondary objectives will be to collect data on the objectives of the definitive study. These objectives are the following:

1) To compare injury-related complications among women presenting at a fracture clinic who disclose a history of IPV versus those who do not disclose IPV over 12 months following a musculoskeletal injury

2) To determine how a history of IPV affects return to pre-injury function

3) To determine the extent to which new episodes of IPV (incident cases) occur after a musculoskeletal injury in women with no prior history of abuse over a 12 month period

4) Among women who disclose a history of IPV versus those who do not disclose IPV, what are the relative utilization and associated costs of health, legal,

and social support services

5) Among women with musculoskeletal injuries who self-report a history of IPV,

we aim to describe changes in abuse severity and type of abuse (physical,

emotional, and/or sexual IPV) over a 12 month period

6) Among women with musculoskeletal injuries who self-report a history of IPV

we aim to determine how a history of IPV affects health-related quality of life

after a musculoskeletal injury

7) Among women with musculoskeletal injuries who self-report a history of IPV

we aim to determine how women*s stage of change based on the Domestic Violence

Survivor Assessment (DVSA) changes over time after a musculoskeletal injury.

Study description

Background summary

1 in 6 women in fracture clinics have experienced intimate partner violence (IPV) in the past year, and 1 in 50 women present to fracture clinics with IPV-related injuries. Orthopaedic health care professionals are in a good position to identify women experiencing IPV and preventing future abuse. There is currently no information on how IPV experiences affect orthopaedic outcomes. Additionally, women with musculoskeletal injuries may experience changing relationship dynamics that affect IPV patterns.

Study objective

The primary objectives are to determine the feasibility of a multi-national prospective cohort study:
1) Assess our ability to recruit women across clinical sites and compare actual recruitment rates to our current estimates;
2) Evaluate adherence to the study protocol, including application of eligibility criteria;
3) Assess our ability to follow and collect data for 12 months;
4) Identify and resolve any problems with data quality;
5) Examine adherence to questionnaire completion;
6) Obtain preliminary estimates of increasing severity of IPV and cases of new

abuse (incident cases) among injured women.

Study design

Multi-centre pilot prospective cohort study.

Study burden and risks

Study participant will spend about 30 minutes to complete questionaires at inclusion and 1, 3, 6, and 12 months later. Patiens will be offered the posibility to answer the questions by telephone.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Adult females (at least 18 years of age)
2) Patients presenting within 6 weeks of their musculoskeletal injury
3) Patients presenting with a fracture or dislocation which is being managed with either surgical or non-surgical treatment

Exclusion criteria

1) Unwilling to or unable to provide consent
2) Unable to complete the study questionnaires in a private location, due to safety and confidentiality
3) Unwilling or unable to follow the study protocol or their attending surgeon has concerns about their ability or willingness to follow study protocols
4) Does not speak and write in Dutch

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-07-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	18-04-2017

Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02529267
CCMO	NL58932.075.16