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Rehabilitation for humeral fractures in working ages

Submission date
27/10/2019

Recruitment status
No longer recruiting

Registration date
16/12/2019

Overall study status
Completed

Last Edited
22/03/2021

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Although programmes based on exercises may be recommended after surgery for proximal humeral fractures, there is a lack of evidence about their clinical impact as well as their long-term effects in working adults as most studies are conducted in older ages. Evidence is also required when defining characteristics (general physiotherapy, mainly including strengthening, stretching, and mobilization exercises, or task-oriented exercises, primarily aimed at early functional recovery and independence in ADL), intensity, frequency and duration of exercise-based programmes. The aim of this study is to find out whether a 12-week rehabilitation programme of functional exercises improves disability, pain, and quality of life, and whether these positive effects are maintained up to at least one year later.

Who can participate?
Patients aged 20-65 undergoing surgical treatment of proximal humeral fractures

What does the study involve?
Participants are randomly allocated to one of two treatment programmes: either an enriched programme incorporating task-oriented exercises, or general physiotherapy alone. The treatment programmes last 12 weeks, the rehab sessions are performed three times a week and the duration is 1 hour. The follow-up is for 1 year.

What are the possible benefits and risks of participating?
Possible benefits are clinically significant improvements in disability, pain, and quality of life. No side effects are expected.

Where is the study run from?
Operative Unit of the Scientific Institute of Lissone, Monza Brianza (Italy)

When is the study starting and how long is it expected to run for?
May 2012 to June 2017

Who is funding the study?
University of Cagliari, UNICA (Italy)

Who is the main contact?
Marco Monticone
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
4/2012

Study information

Scientific Title
Task-oriented exercises improve disability of working adults with surgically treated proximal humeral fractures: a randomized controlled trial with one-year follow-up

Study objectives
A 12-week rehabilitation programme of functional exercises would produce clinically significant improvements in disability, pain, and quality of life (QoL) in these subjects vs. general physiotherapy, and that these positive effects would have maintained up to at least one year later.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/05/2012, Ethical Committee Salvatore Maugeri Foundation (Via Monsignor Ennio Bernasconi, 16, 20851 Lissone MB, Italy; +39 (0)39 4657277; no email provided), ref: 4

Study design
Randomised parallel-group superiority-controlled 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 contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Proximal humeral fracture, following surgery

Interventions
Experimental group. Task-oriented exercises and occupational therapy.
Control group. Passive humeral and upper limb mobilisation, strengthening, muscle segmentary stretching, and
postural control.

Randomization: the biostatistician randomized the subjects to one of the two treatment programmes using a permuted-block randomization procedure. The list of treatment codes was previously generated and stored in Matlab and an automatic assignment system, also developed in Matlab, was used to conceal the allocation.

The treatment programme took place at the outpatient rehabilitative gym at the hospital and was led by two physiatrists, an occupational therapist, and two equally-experienced physiotherapists. The interventions lasted 12 weeks, the rehab sessions were performed three times a week and the duration was of 1 hour. The follow-up was of 1 year. During the treatment period, the questionnaires were administered by secretarial staff who checked them and returned any uncompleted part to the subjects for completion. At follow-up, the patients were contacted personally by the same secretarial staff in order to ensure that the questionnaires were properly completed.

Intervention Type
Procedure/Surgery

Primary outcome measure
Disability assessed using the validated Italian version of the self-reported Disability Arm Shoulder Hand questionnaire before treatment, at the end (12 weeks) and at follow-up (one year after the end of treatment).

Secondary outcome measures
1. Pain intensity assessed using an 11-point numerical rating scale at baseline, 12 weeks and 12 months
2. Quality of life assessed using the Italian version of the self-report Short-Form Health Survey (SF-36) at baseline, 12 weeks and 12 months
3. Patient-rated efficacy of treatment assessed using the Global Perceived Effect scale (GPE) at end of treatment

Overall study start date
01/05/2012

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Subjects undergoing surgical treatment of PHFs classified as Arbeitsgemeinschaft Osteosynthese (AO) Foundation for the Study of Internal Fixation type 11 (2)
2. A good understanding of Italian
3. Working age (20-65 years old)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
70

Total final enrolment
70

Key exclusion criteria
1. Cognitive impairment (Mini-Mental State Examination Score of<24), unstable cardiovascular and pulmonary diseases, and systemic or neuromuscular diseases, ruled out by means of case histories and imaging
2. Subjects with isolated tuberculum majus fracture (AO 11, A1), or fractures with involvement of the glenoid cavity, double fractures or injury of the plexus or the axillary nerve
3. Subjects who had workers’ compensation

Date of first enrolment
01/06/2012

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
Italy

Lao People's Democratic Republic

Study participating centre
Scientific Institute of Lissone
Via Monsignor Bernasconi, 16
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Sponsor information

Organisation
Università degli Studi di Cagliari

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Sponsor type
University/education

Website
https://www.unica.it/unica/it/dip_scienzemedsanpub.page

Funder(s)

Funder type

University/education

Funder Name
Università degli Studi di Cagliari

Alternative Name(s)
Università degli Studi di Cagliari, Università di Cagliari, UNICA

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Italy

Results and Publications

Publication and dissemination plan
Peer-reviewed journals with special interest to spinal disorders. No additional documents are available.

Intention to publish date
31/03/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from Marco Monticone (marco.monticone@unica.it) on reasonable request on publication and from that day on; no access criteria; all of the analyses; consent was obtained; no comments on data anonymisation; no ethical or legal restrictions; no other comments.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/03/2021	22/03/2021	Yes	No