ISRCTN79534571 https://doi.org/10.1186/ISRCTN79534571

Comparing two splint types in the treatment of boxer's fracture (a fracture of one of the bones in the hand)

Submission date
29/03/2019

Recruitment status
No longer recruiting

Registration date
01/04/2019

Overall study status
Completed

Last Edited
03/07/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims:
Hand fractures are the most common fractures of the body, and up to 44 in every 100 fractures in the hand occur in the bones in the palm of the hand and the base of the thumb (metacarpal bones). Fractures of the bone on the outside of the palm below the little finger (fifth metacarpal) are known as boxer’s fractures and are the most common fractures in the hand. Most of them are treated using an ulnar gutter splint (UGS). This involves a hard moulded strip that is bandaged onto the patient's palm and the underside of their forearm to support the hand and prevent movement while the fracture heals. However, treatment of these fractures by preventing movement can lead to complications, such as the bones not healing in correct alignment, stiffness and reduced grip strength. This splint can also be uncomfortable because it limits wrist and finger movements. Other types of splints or wrapping have been tested with positive results. One of these is the functional metacarpal splint (FMS), which is more flexible than the UGS and allows more movement. The aim of this study is to compare UGS and FMS in the treatment of boxer's fractures in terms of the functional and X-ray (radiological) results. The study aims to investigate whether UGS is an unnecessarily restrictive treatment of boxer's fractures. FMS might be adequate to prevent bone loss and result in a faster recovery compared with UGS.

Who can participate?
Healthy volunteers with boxer’s fracture aged between 18-60.

What does the study involve?
Depending on when they are referred for treatment, participants will receive UGS or FMS. Both splints will be removed after 1 month. At months 1 and 6, the participant's hand will be X-rayed so that measurements can be made of the bones. At months 2 and 6, the participants will be asked to fill in a questionnaire about their level of disability related to the fracture and will have their grip strength tested.

What are the possible benefits and risks of participating?
The patients will help us to investigate if any of the treatment is superior to other. Patients in

both groups will be treated for their fracture, there is no benefit other than this. There is no additional risk of participating since both treatments are widely used and considered safe.

Where is the study run from?
Istanbul University Cerrahpasa Medical Faculty Hospital

When is the study starting and how long is it expected to run for?
January 2011 to July 2018

Who is funding the study?
The study was funded by investigators.

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
77303040

Study information

Scientific Title
Comparison of functional metacarpal splint and ulnar gutter splint in the treatment of fifth metacarpal neck fractures: A prospective comparative study

Study objectives
Functional metacarpal splint yields better clinical outcomes compared to ulnar gutter splint in the treatment of fifth metacarpal neck fractures

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/04/2011, Istanbul University Cerrahpasa Medical Faculty - Clinical Research Ethics Committee (34303 Cerrahpaşa, Istanbul, Turkey; 0212 414 3000; ctfpersonel@istanbul.edu.tr), ref: 77303040-804.01-I

Study design
Single-centre, quasi-randomised, comparative study.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Fifth metacarpal neck fractures

Interventions
Functional metacarpal splint and ulnar gutter splint interventions were applied. Two different treatment plans were applied to patients in a consecutive manner based on referral time (quasi-randomisation).

The ulnar gutter splint was applied from the medial side of the hand and the forearm with the wrist at 30° extension, the metacarpophalangeal (MCP) joint at 70° flexion and the proximal interphalangeal (PIP) joint at full extension. The splint was removed at the end of the first month. The patients were followed up for 6 months.

The functional metacarpal splint was placed according to the 3-point principle (one dorsal, two volar). The dorsal contact point was over the fracture site. One volar contact point was located over the metacarpal head, and one volar contact point was located over the metacarpal shaft. It does not limit the motion of MCP and wrist joints. The splint length was similar to metacarpal length. The splint was removed at the end of the first month. The patients were followed up for 6 months.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Functional outcome score (symptoms and extent of disability) assessed using the Disabilities of the Arm, Shoulder and Hand Score (QuickDash) at month 2 and month 6

Mean, standard deviation (SD), median, frequency, ratio, and minimum and maximum values were used as descriptive statistical methods. Student t test was used for two-group comparisons of quantitative data with a normal distribution, and Mann-Whitney U test was used for two-group comparisons of data without a normal distribution. Paired sample t-test was used for intragroup comparison of parameters with a normal distribution, and a Wilcoxon Signed Rank test was used for intragroup comparison of parameters without a normal distribution. In the analysis of follow-up values with a normal distribution, two-way ANOVA test was used to

evaluate the variables, and the Bonferroni test was used to evaluate binary comparisons. P values were multiplied by six for Bonferroni correction. In the analysis of follow-up values without a normal distribution, the Wilcoxon Signed Rank test was used to evaluate the variables, and the Friedman test was used to evaluate binary comparisons. Statistical significance was set as p <0.05.

Key secondary outcome(s))
1. Angulation assessed using angle measurement on direct radiographs at injury day (before and after fracture reduction), month 1 and month 6
2. Shortening assessed using shortening measurement on direct radiographs at injury day (before and after fracture reduction), month 1 and month 6
3. Grip strength assessed using a hand dynamometer at month 2 and month 6

Mean, standard deviation (SD), median, frequency, ratio, and minimum and maximum values were used as descriptive statistical methods. Student t test was used for two-group comparisons of quantitative data with a normal distribution, and Mann-Whitney U test was used for two-group comparisons of data without a normal distribution. Paired sample t-test was used for intragroup comparison of parameters with a normal distribution, and a Wilcoxon Signed Rank test was used for intragroup comparison of parameters without a normal distribution. In the analysis of follow-up values with a normal distribution, two-way ANOVA test was used to evaluate the variables, and the Bonferroni test was used to evaluate binary comparisons. P values were multiplied by six for Bonferroni correction. In the analysis of follow-up values without a normal distribution, the Wilcoxon Signed Rank test was used to evaluate the variables, and the Friedman test was used to evaluate binary comparisons. Statistical significance was set as p <0.05.

Completion date
01/07/2018

Eligibility

Key inclusion criteria
1. Isolated and closed neck fractures of the fifth metacarpal with no rotational deformity or associated injury
2. Aged 18-60 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
40

Key exclusion criteria
Unstable, open, comminuted or intraarticular metacarpal neck fractures

Date of first enrolment
01/01/2012

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Türkiye

Study participating centre
Istanbul University-Cerrahpasa
Kocamustafapasa cad. No:53
Istanbul
Türkiye
34093

Sponsor information

Organisation
Istanbul University-Cerrahpasa

ROR
https://ror.org/01dzn5f42

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/04/2019	03/07/2019	Yes	No