ISRCTN10831351 https://doi.org/10.1186/ISRCTN10831351

Clinical and surgical parameters can be combined to predict how long it will take a tibia fracture to heal

Submission date
29/06/2017

Recruitment status
No longer recruiting

Registration date
30/06/2017

Overall study status
Completed

Last Edited
26/11/2021

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Healing of tibia (the large bone in the leg) fractures occurs over a wide time range, from a minimum of two months to a maximum of six months in most patients. In a significant percentage of patients, healing may take place well beyond six months after the trauma or may require one or more surgical procedures, with significant associated health costs. Although general and local conditions that may adversely affect fracture healing have been identified, the ability to early recognise fractures at risk of developing a non-union (failure of healing) is still left to the surgeon's experience. The FRACTING score has been developed by using data about clinical data that is used to predict the risk of a bone to non-union. This score can be used to predict how long is needed for healing. This score may be able to identify patients who are at risk of non-union and this can allow them to pursue different treatments, resulting in reduced disability time and health cost savings. The aim of this study is to investigate the capability of the FRACTING score, calculated soon after fracture treatment to predict fracture healing time.

Who can participate?
Adults aged 18 and older who have a fracture.

What does the study involve?
Participants are suffered a tibia fracture receive their routine treatment and follow up care. During their follow up, clinical data about their healing is collected in a dedicated software and a score is used to calculate their risk of failure to healing.

What are the possible benefits and risks of participating?
Participants may benefit from knowing their score in order to receive customized treatment protocols by planning closer surveillance and specific rehabilitation. There are no risks with participating.

Where is the study run from?
This study is being run by IGEA SpA (Italy) and takes place in 40 Orthopaedic Traumatology centres (Italy).

When is the study starting and how long is it expected to run for?
January 2009 to October 2014

Who is funding the study?
IGEA SpA (Italy)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
The FRACTING study

Study information

Scientific Title
The FRACTING (tibia FRACTure prediction healING days) Study: Can clinical and surgical parameters be combined to predict how long it will take a tibia fracture to heal? A prospective multicentre observational study

Acronym

The FRACTING study

Study objectives
Healing of tibia fractures occurs over a wide time range (2 to >12 months) with a number of general and local factors contributing to prolonged healing. The aim of this study is to investigate the capability of the FRACTING score, calculated soon after fracture treatment to predict fracture healing time.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee University of Ferrara Italy, 29/09/2011

Study design
This prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Patients who had suffered a tibia fracture.

Interventions
Patients who had suffered a tibia fracture were recruited in 40 Italian orthopaedic traumatology centres to be surgically treated. The patient's treatment and the time of follow-up were left to the choice of the trauma surgeon based on experience.
During the follow-up, clinical data about the healing is collected in a dedicated software and used to calculate the score to identify fractures at risk of non-union. Drop down menu was used for descriptive variables. Required fields ensured complete and consistent data collection.The score is calculated adding all values. Information on patient health, fracture morphology and surgical treatment adopted was combined to calculate the FRACTING score. Fractures were considered healed when the patient was able to fully weight-bear without pain. Within 12 months from trauma, the date at which the fracture healed was used to calculate days and months elapsed since treatment (“healing time”).

Intervention Type
Other

Primary outcome measure
Time to healing of a tibia fracture is calculated by correlating surgical and clinical data in a dedicated software used to calculate the score: score versus healing time.

Secondary outcome measures
Ability of the score to identify fractures at risk of non-union healing after more than six months.

Overall study start date
12/01/2009

Completion date
24/10/2014

Eligibility

Key inclusion criteria
1. Patients with post-traumatic fractures type 41-A and B, 42-A-B and C, 43-A and B according to AO classification
2. Fracture treatment within 3 days from trauma
3. Patient age >18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
519

Total final enrolment
363

Key exclusion criteria
1. Fractures involving the tibia plateau and malleolar fractures
2. Patients with autoimmune diseases or neoplasia
3. Patients who could not return to the treating centre for follow-up visits

Date of first enrolment
01/02/2010

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
Italy

Study participating centre
40 Italian orthopaedic traumatology centres
Italy
44121 Ferrara coordinating center

Sponsor information

Organisation
IGEA SpA

Sponsor details
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Sponsor type
Industry

Website
http://www.igeamedical.com/about-us/innovation-over-thirty-years

ROR
https://ror.org/01bws2668

Funder(s)

Funder type
Industry

Funder Name
IGEA SpA

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/07/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Francesca De Terlizzi at f.deterlizzi@igeamedical.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/04/2018	26/11/2021	Yes	No