

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	<input type="checkbox"/> Prospectively registered
Registration date 30/06/2017	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/11/2021	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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?
Dr Stefania Setti
s.setti@igeamedical.com

Contact information

Type(s)
Scientific

Contact name
Dr Stefania Setti

ORCID ID
<https://orcid.org/0000-0001-8990-5452>

Contact details
IGEA SpA
Via Parmenide 10/A
Carpi (Mo)
Italy
41012
+39 059 699 600
s.setti@igeamedical.com

Additional identifiers

Protocol serial number
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

Study type(s)

Prevention

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

ROR

<https://ror.org/01bws2668>

Funder(s)

Funder type

Industry

Funder Name

IGEA SpA

Results and Publications

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