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Identifying molecules in the blood associated with long term healing problems in long bone fractures

Submission date	Recruitment status	[ ] Prospectively registered
05/04/2020	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/05/2020	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/06/2020	Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
Some broken bones do not heal even when they get the best surgical or nonsurgical treatment. In some cases, certain risk factors make it more likely that a bone will fail to heal. When a broken bone fails to heal it is called a "nonunion." Incomplete fracture healing may lead to chronic nonunion, thus determining fracture healing is the basic issue in clinical treatment. However, there are no validated molecules in the blood (biomarkers) for p chronic nonunion. In this study, bioinformatics analysis combined with the experimental verification strategy was used to identify blood biomarkers for chronic nonunion.

Who can participate?
Patients diagnosed with open fractures of long bone and defined non-union.

What does the study involve?
Participants will provide a single blood sample for analysis.

What are the possible benefits and risks of participating?
None explaected.

Where is the study run from?
Xuanwu Hospital of Capital Medical University (China)

When is the study starting and how long is it expected to run for?
August 2018 to October 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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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
Nil known

Study information

Scientific Title
Bioinformatic analysis and experimental identification of blood biomarkers for chronic nonunion

Study objectives
Incomplete fracture healing may lead to chronic nonunion, thus determining fracture healing is the basic issue in clinical treatment. However, there were no validated early diagnose biomarkers for assessing chronic nonunion. In this study, bioinformatics analysis combined with the experimental verification strategy was used to identify blood biomarkers for chronic nonunion.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 13/07/2018, Ethics Committee of Xuanwu Hospital, Capital Medical University (Chuangchun Street No.45, Beijing, China, 100053; +86-010-8319-9270; xwkyethics@163.com), ref: XW-2018-135.

Study design
Observational

Primary study design
Observational

Secondary study design
Ecological study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Nonunion of open fractures of long bone

Interventions
Patients admitted to the Department of Orthopedics of Xuanwu Hospital between August 2018 and July 2019, are enrolled in this study. The group is categorized into the Healed and Nonunion groups, according to the FDA diagnostic criteria amendment. The FDA defines nonunion as a fractured bone that has not completely healed within 9 months following injury and without signs of healing for at least 3 months.
In this study, 9 months was chosen as the time point to define the nonunion.

Bioinformatics analysis combined with the experimental verification strategy was used to identify blood biomarkers for chronic nonunion. First, chronic nonunion differential expressed genes were identified by microarray data analysis. Second, Dipsaci Radix (DR), traditional Chinese medicine for fracture treatment, was used to screen the target genes. Third, the drug-compound-target-disease network was determined, and the biomarker genes were obtained. Finally, the potential blood biomarkers were verified by ELISA and qPCR methods.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dipsaci Radix

Primary outcome measure
Biomarkers verified by ELISA and qPCR methods from a blood sample taken at a single time point

Secondary outcome measures
None

Overall study start date
01/05/2018

Completion date
31/10/2019

Eligibility

Key inclusion criteria
Patients diagnosed with open fractures of long bone and defined nonunion

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Total final enrolment
55

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/08/2018

Date of final enrolment
31/07/2019

Locations

Countries of recruitment
China

Study participating centre
Xuanwu Hospital of Capital Medical University
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Sponsor information

Organisation
Xuan Wu Hospital of the Capital Medical University

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00k7r7f88

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
01/08/2020

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/06/2020	08/06/2020	Yes	No