

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

<b>Submission date</b> 05/04/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 04/05/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/06/2020	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## 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?

Dr Limin Liu

xwllm2019@sina.com

# Contact information

## Type(s)

Scientific

## Contact name

Dr Limin Liu

## ORCID ID

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## Contact details

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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

Changchun Street No.45

Beijing

China  
100053

## Sponsor information

### Organisation

Xuan Wu Hospital of the Capital Medical University

### Sponsor details

Changchun Street No.45  
Beijing  
China  
100053  
+86-138-1051-7806  
edmond\_pku@163.com

### 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?
<a href="#">Results article</a>	results	05/06/2020	08/06/2020	Yes	No