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

Submission date	Recruitment status  No longer recruiting	Prospectively registered		
05/04/2020		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
04/05/2020		[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? 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

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

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

## Study type(s)

Diagnostic

## 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(s)

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

# Key secondary outcome(s))

None

## Completion date

31/10/2019

# **Eligibility**

## Key inclusion criteria

Patients diagnosed with open fractures of long bone and defined nonunion

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

### Sex

All

## 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

## **ROR**

https://ror.org/00k7r7f88

# Funder(s)

# Funder type

Other

## **Funder Name**

Investigator initiated and funded

# **Results and Publications**

# 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes