ORTHOpedic randomized clinical trial with expanded bone marrow MSC and bioceramics versus autograft in long bone nonUNIONs

Fact Sheet

Project Information

ORTHOUNION
Grant agreement ID: 733288

Funded under
SOCIETAL CHALLENGES - Health, demographic change and well-being

Total cost
€ 5 999 150,87

EU contribution
€ 5 999 150,87

Closed project

Coordinated by
UNIVERSIDAD AUTONOMA DE MADRID
Spain

Start date
1 January 2017

End date
30 June 2022

Objective

Current orthopaedic treatments permit spontaneous bone regeneration to unite and heal 90% bone injuries. Non-union associates pain and disability, often requiring biological enhancement. Regenerative medicine research suggests to the general
public that alternative treatments based on advanced therapy medicinal products (ATMP) are already available. However, early clinical trials only explore its potential benefit. Underreported results and absence of early trial confirmation in adequately powered prospective randomized clinical trials (RCT) indicate that evidence is not available to transfer any technique into routine clinical application.

This ORTHOUNION Project was developed from FP7-Project (REBORNE). Its results confirmed 92% bone healing rate (Gómez-Barrena et al, 2016 submitted manuscript) with an autologous ATMP of GMP expanded bone marrow derived human MSC in non-unions, where the reported bone healing rate after surgery with standard bone autograft is 74%. Any further development requires adequately powered prospective RCTs. This will be the main aim of ORTHOUNION: to assess clinically relevant efficacy of an autologous ATMP with GMP multicentric production in a well-designed, randomized, controlled, three-arm clinical trial under GCP, versus bone autograft, gold-standard in fracture non-unions. A non-inferiority analysis will evaluate if cell dose can be lowered. ATMP has been authorized by the National Competent Authorities of the participating countries in 3 previous trials (REBORNE) and will be monitored by ECRIN-ERIC to ensure quality and credibility of RCT results.

Secondary aims include innovative strategies to increase manufacturing capacity and lower costs to pave translation into routine clinical treatments, biomaterial refinement to facilitate surgery, personalized medicine supportive instruments for patient selection and monitoring, and health economic evaluation. Results in this project may help define the future of bone regenerative medicin

Fields of science

- medical and health sciences > clinical medicine > surgery
- medical and health sciences > basic medicine > pharmacology and pharmacy > pharmaceutical drugs
- natural sciences > chemical sciences > inorganic chemistry > alkaline earth metals
- medical and health sciences > health sciences > personalized medicine
- engineering and technology > industrial biotechnology > biomaterials

Keywords

- Bone regeneration
- expanded Bone Marrow derived MSCs
- regulatory approved IMP
- long bone fracture non-union
- avascular necrosis of the femoral head
- multicentric comparative clinical trials
Programme(s)

H2020-EU.3.1. - SOCIETAL CHALLENGES - Health, demographic change and well-being

H2020-EU.3.1.3. - Treating and managing disease

Topic(s)

SC1-PM-11-2016-2017 - Clinical research on regenerative medicine

Call for proposal

H2020-SC1-2016-2017

See other projects for this call

Sub call

H2020-SC1-2016-RTD

Funding Scheme

RIA - Research and Innovation action

Coordinator

UNIVERSIDAD AUTONOMA DE MADRID

Net EU contribution

€ 824 210,01

Address

Calle einstein 3 ciudad univ cantoblanco rectorado
28049 Madrid

Spain

Region

Comunidad de Madrid > Comunidad de Madrid > Madrid

Activity type

Higher or Secondary Education Establishments
Participants (16)

SERVICIO MADRILENO DE SALUD
Spain
Net EU contribution
€ 661 552,11
Address
Plaza carlos trias bertran 7
28020 Madrid
Region
Comunidad de Madrid > Comunidad de Madrid > Madrid
Activity type
Public bodies (excluding Research Organisations and Secondary or Higher Education Establishments)

THIRD-PARTY

FUNDACION PARA LA INVESTIGACION BIOMEDICA DEL HOSPITAL UNIVERSITARIO PUERTA DE HIERRO-MAJADAHONDA
Spain
Net EU contribution
€ 612 416,46
Address
Joaquin rodrigo 2
28222 Majadahonda

Region
Comunidad de Madrid > Comunidad de Madrid > Madrid

Activity type
Research Organisations

Links
Contact the organisation
Participation in EU R&I programmes
HORIZON collaboration network

Other funding
€ 0,00

THIRD-PARTY

FUNDACION PARA LA INVESTIGACION BIOMEDICA DEL HOSPITAL UNIVERSIATRIO LA PAZ

Spain
Net EU contribution
€ 78 087,43

Address
Paseo de la castellana 261
28046 Madrid

Region
Comunidad de Madrid > Comunidad de Madrid > Madrid

Activity type
Other

Links
Contact the organisation
Participation in EU R&I programmes
HORIZON collaboration network

Other funding
€ 0,00

ETABLISSEMENT FRANCAIS DU SANG

France
UNIVERSITAET ULM

Germany

Net EU contribution
€ 998 476,63

Address
Helmholtzstrasse 16
89081 Ulm

Region
Baden-Württemberg > Tübingen > Ulm, Stadtkreis

Activity type
Higher or Secondary Education Establishments

Links
Contact the organisation
Participation in EU R&I programmes
HORIZON collaboration network

Other funding
€ 0,00
INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE

France
Net EU contribution
€ 221 230,00
Address
Rue de tolibiac 101
75654 Paris
Region
Ile-de-France > Ile-de-France > Paris
Activity type
Research Organisations
Links
Contact the organisation Website Participation in EU R&I programmes HORIZON collaboration network
Other funding
€ 0,00

ECRIN EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

France
Net EU contribution
€ 285 956,50
Address
30 bd saint-jacques batiment b
75014 Paris
Region
Ile-de-France > Ile-de-France > Paris
Activity type
Research Organisations
Links
Contact the organisation Website Participation in EU R&I programmes HORIZON collaboration network
Other funding
€ 0,00

THIRD-PARTY

HEINRICH-HEINE-UNIVERSITAET DUESSELDORF

Germany
Net EU contribution
€ 0,00
Address
Universitaetsstrasse 1
40225 Dusseldorf
Region
Nordrhein-Westfalen > Düsseldorf > Düsseldorf, Kreisfreie Stadt
Activity type
Higher or Secondary Education Establishments
Links
Contact the organisation Website Participation in EU R&I programmes HORIZON collaboration network
Other funding
€ 0,00

THIRD-PARTY

FUNDACIO DE RECERCA CLINIC BARCELONA-INSTITUT D INVESTIGACIONS BIOMEDIQUES AUGUST PI I SUNYER

Spain
Net EU contribution
€ 190 450,00
Address
Carrer rossello 149
08036 Barcelona
Region
Este > Cataluña > Barcelona
Activity type
Research Organisations
THIRD-PARTY

UNIVERSITAETS KLINIKUM FREIBURG

Germany

Net EU contribution

€ 97,287.50

Address

Hugstetter strasse 49
79106 Freiburg

Region

Baden-Württemberg > Freiburg > Freiburg im Breisgau, Stadtkreis

Activity type

Higher or Secondary Education Establishments

Links

Contact the organisation  Website  Participation in EU R&I programmes  HORIZON collaboration network

Other funding

€ 0,00

CENTRE HOSPITALIER REGIONAL UNIVERSITAIRE DE TOURS

France

Net EU contribution

€ 193,125.00

Address

Boulevard tonelle 2
37044 Tours cedex 9

Region

Centre — Val de Loire > Centre — Val de Loire > Indre-et-Loire
**ISTITUTO ORTOPEDICO RIZZOLI**

*Italy*

Net EU contribution  
€ 402,117.35

Address  
Via di barbiano 1/10  
40136 Bologna

Region  
Nord-Est > Emilia-Romagna > Bologna

**ALMA MATER STUDIORUM - UNIVERSITA DI BOLOGNA**

*Italy*

Net EU contribution  
€ 47,806.13

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40126 Bologna
UNIVERSITA DEGLI STUDI DI MODENA E REGGIO EMILIA

Italy

Net EU contribution
€ 293,680,00

Address
Via universita 4
41121 Modena

Region
Nord-Est > Emilia-Romagna > Modena

Activity type
Higher or Secondary Education Establishments

Links
Contact the organisation  Website  Participation in EU R&I programmes  HORIZON collaboration network

Other funding
€ 0,00

FONDAZIONE IRCCS CA’ GRANDA - OSPEDALE MAGGIORE POLICLINICO

Italy

Net EU contribution
€ 420,950,00

Address
Via francesco sforza 28
20122 Milano

Region
Nord-Ovest > Lombardia > Milano

Activity type
Other

Links
Contact the organisation Website Participation in EU R&I programmes HORIZON collaboration network

Other funding
€ 0,00

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BIOMATLANTE

France

Net EU contribution
€ 277 062,50

Address
5 rue edouard belin - za des iv nations
44360 Vigneux de bretagne

SME
Yes

Region
Pays de la Loire > Pays de la Loire > Loire-Atlantique

Activity type
Private for-profit entities (excluding Higher or Secondary Education Establishments)

Links
Contact the organisation Participation in EU R&I programmes HORIZON collaboration network

Other funding
€ 0,00

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