Restoring tissue regeneration in patients with visceral Graft versus Host Disease.

Fact Sheet

Project Information

<table>
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<th>RETHRIM</th>
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<td>Grant agreement ID: 643580</td>
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Funded under H2020-EU.3.1.3.

Overall budget € 5 857 587,50

EU contribution € 5 857 587,50

ACADEMISCH ZIEKENHUIS LEIDEN Netherlands

Start date 1 January 2015
End date 31 December 2021

Objective

Stem cell regenerative therapies hold great promise for patients suffering from a variety of disorders that are associated with tissue or organ injury. Regeneration relies on tissue or organ-specific stem and progenitor cells, but can also aim at promoting the endogenous repair capacity of the body.

Mesenchymal stromal cells (MSC) are undergoing clinical testing in a variety of clinical conditions aiming at repair through direct or indirect mechanisms. Their ability to form bone or cartilage is used to directly repair these tissues. In other conditions their regenerative effects are based on endogenous repair through their anti-inflammatory properties. The latter mechanism is important in the treatment of acute Graft-versus-Host Disease (GvHD). We have been involved in the clinical development from the beginning and we have shown the therapeutic potential.
However, no results of controlled randomized phase 3 studies have been published to date, thereby hampering safety and efficacy assessment.

Within our consortium we have developed an academic infrastructure for the harmonized production of MSC. In the RETHRIM proposal this will be combined with our clinical expertise to conduct the first Europe-wide placebo controlled randomized phase III trial using MSC regenerative therapy for the treatment of steroid-resistant visceral GvHD. Central to the RETHRIM project is the clinical trial for which 150 patients will be recruited. All MSC products will be extensively analysed using molecular and functional markers, in order to develop a potency signature for the product and for the prediction of response. We also intend to collect data from additional quality of life, health technology assessment and ethical studies. We will apply for an Orphan Drug Designation in Europe and this may serve as a stepping-stone for the further commercialization of the MSC product, once a positive outcome has been obtained.

**Fields of science**

> > >
> > >
> >

**Programme(s)**

**Topic(s)**

**Call for proposal**

H2020-PHC-2014-single-stage

**Funding Scheme**

RIA - Research and Innovation action

**Coordinator**

ACADEMISCH ZIEKENHUIS LEIDEN

Address

Activity type

EU contribution

€ 2 334 931,25
Participants (11)

**KAROLINSKA INSTITUTET**
- **Sweden**
- EU contribution: € 229,912.50
- Address: Nobels Vag 5, 17177 Stockholm
- Activity type: Higher or Secondary Education Establishments

**OSPEDALE PEDIATRICO BAMBINO GESU**
- **Italy**
- EU contribution: € 331,537.50
- Address: Piazza Sant Onofrio 4, 00165 Roma
- Activity type: Research Organisations

**UNIVERSITAET LEIPZIG**
- **Germany**
- EU contribution: € 660,043.75
- Address: Ritterstrasse 26, 04109 Leipzig
- Activity type: Higher or Secondary Education Establishments

**KATHOLIEKE UNIVERSITEIT LEUVEN**
- **Belgium**
- EU contribution: € 354,850
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<tr>
<td><strong>FUNDACION INSTITUTO DE ESTUDIOS DE CIENCIAS DE LA SALUD DE CASTILLA Y LEON</strong></td>
<td>Spain</td>
<td>€ 399 787,50</td>
<td>Parque Santa Clara 42002 Soria</td>
<td>Research Organisations</td>
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<tr>
<td><strong>ERASMUS UNIVERSITEIT ROTTERDAM</strong></td>
<td>Netherlands</td>
<td>€ 309 300</td>
<td>Burgemeester Oudlaan 50 3062 PA Rotterdam</td>
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<td><strong>LUNDS UNIVERSITET</strong></td>
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<td>€ 333 200</td>
<td>Paradisgatan 5C 22100 Lund</td>
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<td><strong>IMMUNOTOOLS GMBH</strong></td>
<td>Germany</td>
<td>€ 534 025</td>
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GENOMIC INVESTMENTS BV
- Netherlands
- EU contribution: € 0
- Address: Plesmanlaan 1D, 2333 BZ Leiden
- Activity type: Private for-profit entities (excluding Higher or Secondary Education Establishments)
- Website
- Contact the organisation

STICHTING HEMATO-ONCOLOGIE VOOR VOLWASSENEN NEDERLAND (HOVON)
- Netherlands
- EU contribution: € 0
- Address: De Boelelaan 1117, 1081 HV Amsterdam
- Activity type: Research Organisations
- Contact the organisation

GenomeScan B.V.
- Netherlands
- EU contribution: € 370 000
- Address: Plesmanlaan 1D, 2333 BZ Leiden
- Activity type: Private for-profit entities (excluding Higher or Secondary Education Establishments)
- Website
- Contact the organisation