Does vascular endothelial growth factor gene therapy safely improve outcome in severe early-onset fetal growth restriction?

From 2013-01-01 to 2018-12-31, closed project | EVERREST Website

Project details

<table>
<thead>
<tr>
<th>Total cost:</th>
<th>Topic(s):</th>
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<tr>
<td>EUR 7 766 112</td>
<td>HEALTH.2012.1.4-4 - Targeted nucleic acid delivery as an innovative therapeutic or prophylactic approach</td>
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<td>EU contribution:</td>
<td>Call for proposal:</td>
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<td>EUR 5 998 984</td>
<td>FP7-HEALTH-2012-INNOVATION-1</td>
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<td>Coordinated in:</td>
<td>Funding scheme:</td>
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<tr>
<td>United Kingdom</td>
<td>CP-FP - Small or medium-scale focused research project</td>
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Objective

Fetal growth restriction (FGR) globally occurs in 8% of pregnancies, is severe and early onset in 1:500 cases, affecting 11,000 babies annually in the EU. In most cases, reduced uterine blood flow restricts substrate delivery to the fetus causing growth to slow or cease. There is no treatment. Currently the fetus is delivered very preterm before fetal death or irreversible organ damage occurs. Affected neonates suffer intracranial haemorrhage, chronic lung disease, cerebral palsy, with heart disease and diabetes as adults; mortality is high. Recent improvements in the care of premature growth restricted neonates, means that more of them survive delivery, but at great cost. Small increases in fetal growth and gestation at birth are associated with major improvements in survival and morbidity.

Improving uterine blood flow is key and Vascular Endothelial Growth Factor (VEGF) is important to achieve this. In preclinical animal models we showed that local VEGF gene transfer to the uteroplacental circulation using adenovirus vectors increases uterine blood flow, attenuates constriction of uterine arteries and increases angiogenesis; these changes result in improved growth of severely growth restricted fetuses. This is the first clinically-applicable evidence based therapy that could improve perinatal outcome in severe early onset FGR in man.

In collaboration with an SME experienced in gene therapy trials, our aim is to complete an agreed toxicology programme, identify specific ethical issues in stakeholders, and to perform a Phase I/II study in women with severe early onset FGR at four EU centres of excellence, using interventional radiology to deliver an adenovirus vector containing the mature processed form of human VEGF-D into the uterine artery. Data on safety, tolerability and efficacy will be analysed, and used, if successful, to inform phase II and III trials of this innovative therapy, leading to the first treatment for this intractable obstetric condition.

Related information

Result In Brief

Therapy for placental insufficiency leading to fetal growth restriction

Report Summaries

Final Report Summary - EVERREST (Does vascular endothelial growth factor gene therapy safely improve outcome in severe early-onset fetal growth restriction?)

Periodic Report Summary 1 - EVERREST (Does vascular endothelial growth factor gene therapy safely improve outcome in severe early-onset fetal growth restriction?)
Periodic Report Summary 2 - EVERREST (Does vascular endothelial growth factor gene therapy safely improve outcome in severe early-onset fetal growth restriction?)

Periodic Report Summary 3 - EVERREST (Does vascular endothelial growth factor gene therapy safely improve outcome in severe early-onset fetal growth restriction?)

Periodic Report Summary 4 - EVERREST (Does vascular endothelial growth factor gene therapy safely improve outcome in severe early-onset fetal growth restriction?)

Coordinator

UNIVERSITY COLLEGE LONDON
GOWER STREET
WC1E 6BT London
United Kingdom

Activity type: Other

Administrative contact: Greta Borg-Carbott
Tel.: +442031083033
Fax: +442078132849
Contact the organisation

Participants

FINVECTOR VISION THERAPIES LIMITED
WHITFIELD STREET 44-46 FLOOR 4
W1T2RJ LONDON
United Kingdom

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

Administrative contact: Mark Docherty
Tel.: +44 7768 461545
Contact the organisation

QUEEN MARY UNIVERSITY OF LONDON
327 MILE END ROAD
E1 4NS LONDON
United Kingdom

Activity type: Higher or Secondary Education Establishments

Administrative contact: Richard Edmund Ashcroft
Tel.: +44 20 7882 3940
Fax: +44 20 7882 7042
Contact the organisation
ITA-SUOMEN YLIOPISTO
YLIOPISTONRANTA 1 E
70211 KUOPIO
Finland
EU contribution: EUR 320 116
See on map

Activity type: Higher or Secondary Education Establishments

Administrative contact: Jaana Backman
Tel.: +358505554446
Fax: +35817162187

Contact the organisation

UNIVERSITAETSKLINIKUM HAMBURG-EPPENDORF
Martinistrasse 52
20251 HAMBURG
Germany
EU contribution: EUR 426 352,20
See on map

Activity type: Higher or Secondary Education Establishments

Administrative contact: Kurt Hecher
Tel.: +49 40 7410 57832
Fax: +49 40 7410 46767

Contact the organisation

CONSORCI INSTITUT D’INVESTIGACIONS BIOMEDIQUES AUGUST PI I SUNYER
CALLE ROSSELLO 149 PUERTA BJS
08036 BARCELONA
Spain
EU contribution: EUR 357 780,40
See on map

Activity type: Higher or Secondary Education Establishments

Administrative contact: Pastora Martinez Samper
Tel.: +34 93 227 5707
Fax: +34 93 227 9205

Contact the organisation

LUNDS UNIVERSITET
Paradisgatan 5c
22100 Lund
Sweden
EU contribution: EUR 520 180,40

Activity type: Higher or Secondary Education Establishments

Administrative contact: Lena Gunnarsson
Tel.: +4646177127

Contact the organisation
EURAM LIMITED
LUCY TOWER STREET TOWER HOUSE
LN1 1XW LINCOLN
United Kingdom

See on map

Activity type: Other

Administrative contact: Andrew Banasik
Tel.: +441159811335

Contact the organisation

UNIVERSITY COLLEGE LONDON HOSPITALS
EUSTON ROAD 250
NW1 2PG LONDON
United Kingdom

See on map

Activity type: Higher or Secondary Education Establishments

Administrative contact: Joe Mwanza
Tel.: +44 2034478030
Fax: +44 2073809937

Contact the organisation

MAGNUS INVENTION MANAGEMENT LTD
GLASSLYN ROAD 39
N8 8RJ LONDON
United Kingdom

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

Administrative contact: Gabrielle Robinson
Tel.: +4420 3282 7567

Contact the organisation

Subjects

Scientific Research

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