Dobutamine for NEOnatal CIRCulatory failure defined by novel biomarkers

From 2011-10-01 to 2018-09-30, closed project | NEO-CIRC Website

**Project details**

<table>
<thead>
<tr>
<th>Total cost:</th>
<th>Topic(s):</th>
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<td>EUR 7 784 422,84</td>
<td>HEALTH-2011.4.2-1 - Investigator-driven clinical trials on off-patent medicines for children</td>
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<tr>
<th>EU contribution:</th>
<th>Funding scheme:</th>
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<tbody>
<tr>
<td>EUR 5 999 167,55</td>
<td>CP-FP - Small or medium-scale focused research project</td>
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<th>Coordinated in:</th>
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<tr>
<td>United Kingdom</td>
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**Objective**

Dobutamine and adrenaline are widely used as second line therapy for systemic hypotension in infants. Dopamine is currently the most widely used first line drug. In neonates, sustained hypotension may, and impaired organ perfusion will, cause brain injury and poor neurodevelopmental outcomes. All three catecholamines are currently used off-label and have different modes of action which may result in potentially harmful haemodynamic effects. No reliable safety or efficacy data exists for the use of these drugs in neonates or newborns. Furthermore, no uniform criteria exist to define hypotension and there is little evidence to support current intervention strategies, which vary widely. Recently, superior vena cava (SVC) flow has been proposed as a more reliable indicator of circulatory failure than low blood pressure and preliminary results suggest Dobutamine is the optimum therapeutic in such cases. NEO-CIRC proposes 1) a randomised placebo controlled trial to provide safety and efficacy data for Dobutamine as a first line inotrope for all gestational ages 2) to perform pre-clinical; pharmacokinetic; pharmacodynamic; metabolomic and pharmacogenomic studies 3) to develop improved biomarkers of hypotension 4) to develop and adapt a formulation of Dobutamine suitable for newborns with the aim to apply for a Paediatric Use Marketing Authorisation. The NEO-CIRC consortium includes international experts in neonatal medicine, pharmacology, pharmacogenomics, drug formulation and pre-clinical neonatal models and an experienced group of experienced multicentre clinical trials NICU's. Outcomes anticipated include improved biomarkers of organ perfusion; a new consensus definition of neonatal circulatory failure and answers to key clinical practice uncertainties, including variability of response to Dobutamine in common pathophysiologies seen in newborn infants impact on longer term developmental outcomes so important to the patients, families and wider society.

**Related information**

**Report Summaries**

- Final Report Summary - NEO-CIRC (Dobutamine for NEOnatal CIRCulatory failure defined by novel biomarkers)
- Periodic Report Summary - NEO-CIRC (Dobutamine for neonatal circulatory failure defined by novel biomarkers)
- Periodic Report Summary 2 - NEO-CIRC (Dobutamine for NEOnatal CIRCulatory failure defined by novel biomarkers)
- Periodic Report Summary 3 - NEO-CIRC (Dobutamine for NEOnatal CIRCulatory failure defined by novel biomarkers)
Coordinator

BRIGHTON AND SUSSEX UNIVERSITY HOSPITALS NHS TRUST
Royal Sussex County Hospital, Eastern Road
BN2 5BE BRIGHTON
United Kingdom

**EU contribution:** EUR 955,780.74

**Activity type:** Research Organisations

**Administrative contact:** Heike Rabe
Tel.: +441273696955
Fax: +44 1273 664435

Contact the organisation

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Participants

INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE
RUE DE TOLBIAC 101
75654 PARIS
France

**EU contribution:** EUR 411,753.60

**Activity type:** Research Organisations

**Administrative contact:** Gerard Pons
Tel.: +33140488219
Fax: +33140488328

Contact the organisation

---

MEDIZINISCHE HOCHSCHULE HANNOVER
Carl-Neuberg-Strasse 1
30625 HANNOVER
Germany

**EU contribution:** EUR 669,570

**Activity type:** Higher or Secondary Education Establishments

**Administrative contact:** Olaf Dammann
Tel.: +49 511 5326825
Fax: +49 511 532 6827

Contact the organisation
EU contribution: EUR 243 371,02

Activity type: Public bodies (excluding Research Organisations and Secondary or Higher Education Establishments)

Administrative contact: Idoia Minguez Alonso
Tel.: +34944536885

Contact the organisation

EU contribution: EUR 461 537

Activity type: Higher or Secondary Education Establishments

Administrative contact: Wolfgang Göpel
Tel.: +494515002555
Fax: +494515006986

Contact the organisation

EU contribution: EUR 508 497,96

Activity type: Higher or Secondary Education Establishments

Administrative contact: Mark Turner
Tel.: +441517024101
Fax: +441517024024

Contact the organisation

EU contribution: EUR 68 091

Activity type: Other

Administrative contact: Claudia Roll
Tel.: +49 2363 975 227
Fax: +49 2363 975 219

Contact the organisation
SERVICIO MADRILENO DE SALUD  
PLAZA CARLOS TRIAS BERTRAN 7  
28020 MADRID  
Spain  
See on map  

**Activity type:** Public bodies (excluding Research Organisations and Secondary or Higher Education Establishments)  

**Administrative contact:** Fernando Cabañas  
Tel.: +34917277362  
Contact the organisation

PROVECA LIMITED  
KECKWICK LANE DARESBURY INNOVATION CENTRE DARESBURY  
WA44FS HALTON  
United Kingdom  

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

**Administrative contact:** Simon Bryson  
Tel.: +4407913048665  
Contact the organisation

KITE INNOVATION (EUROPE) LIMITED  
3M BUCKLEY INNOVATION CENTRE  
HD1 3BD HUDDERSFIELD  
United Kingdom  

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

**Administrative contact:** Fleur Geoghegan  
Tel.: +441484437435  
Contact the organisation

MED LIFE SA [ Participation ended  
CALEA GRIVITEL 365  
010719 BUCURESTI  
Romania  

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

**Administrative contact:** Adrian Loan Toma  
Tel.: +40723188272  
Fax: +40212094050  
Contact the organisation
UNIVERSITATEA DE MEDICINA SI FARMACIE IULIU HATIEGANU CLUJ-NAPOCA
VICTOR BABES STREET 8
400012 Cluj-Napoca
Romania
EU contribution: EUR 150 142

Activity type: Higher or Secondary Education Establishments
Administrative contact: Gabriela Corina Zaharie
Tel.: +40745509505
Fax: +40264450356
Contact the organisation

SEMMELWEIS EGYETEM
ULLOI UTCA 26
1085 BUDAPEST
Hungary
EU contribution: EUR 119 341,80

Activity type: Higher or Secondary Education Establishments
Administrative contact: Miklós Szabó
Tel.: +36208258221
Contact the organisation

PECSI TUDOMANYEGYETEM - UNIVERSITY OF PECS
VASVARI PAL UTCA 4
7622 PECS
Hungary
EU contribution: EUR 119 341,80

Activity type: Higher or Secondary Education Establishments
Administrative contact: Tibor Ertl
Tel.: +675501599
Contact the organisation

Onorach Ltd.
Drumsheugh Gardens 26
EH3 7RN Edinburgh
United Kingdom
EU contribution: EUR 359 200

Activity type: Private for-profit entities (excluding Higher or Secondary Education Establishments)
Administrative contact: Christene Leiper
Tel.: +44 01382561648
Contact the organisation
DYNAKIN SL
Spain
48160 DERIO
Spain

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

Administrative contact: Monica Rodriguez
Tel.: +34944045504
Contact the organisation

GAZI UNIVERSITESI
Turkey
GAZI UNIVERSITESI REKTORLUGU PROJELER KOORDINASYON MERKEZI
06500 ANKARA
Turkey
Activity type: Higher or Secondary Education Establishments

Administrative contact: Ebru Ergenekon
Tel.: +903122026032
Fax: +903122150143
Contact the organisation

TUFTS MEDICAL CENTER, INC CORPORATION
United States
Washington Street 800
02111 Boston
United States

Activity type: Research Organisations

Administrative contact: Ivan Frantz
Tel.: +0016176365000
Contact the organisation

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