Many thanks for completing this protocol in English will all available information

GENERAL INFORMATION

Project title (eng)
Randomized Single-blind Study of Intravenous Maintenance of Remodulin® for the Treatment of Pulmonary Hypertension After Fontan Operation

Acronym *[15 characters max]*

Randomized Single-blind Study of Remodulin® After Fontan Operation
Research Domain (keywords)
Pulmonary hypertension; Fontan operation; Remodulin®

Anticipated number of recruiting centres (+ justification)
Single center

RESEARCH PROJECT

Rational (context and hypothesis)
[max. 450 words]
Pulmonary Hypertension(PH) is a significant contributor to the postoperative morbidity and mortality of congenital heart disease, especially after Fontan operation with univentricular physiology. Mild increase of pulmonary vascular resistance may lead to failure of Fontan circulation. Remodulin® has been approved for the treatment of adults with PH, but little is known about the effects in children with PH after Fontan operation. The study aim is to determine the safety and efficiency of Remodulin® to reduce the pulmonary arterial pressure and prevent PH in children after Fontan operation. Meanwhile pharmacokinetics of the drug were checked with or without the peritoneal dialysis.

Originality and innovative aspects
[max. 200 words]
Determine the safety and efficiency of Remodulin® to reduce the pulmonary arterial pressure and prevent PH in children after Fontan operation. Meanwhile pharmacokinetics of the drug were checked with or without the peritoneal dialysis.

Focus of Research
Pulmonary Hypertension(PH) is a significant contributor to the postoperative morbidity and mortality of congenital heart disease, especially after Fontan operation with univentricular physiology.Remodulin® has been approved for the treatment of adults with PH, but little is known about the effects in children with PH after Fontan operation.

Keywords [5]
Remodulin®;pulmonary vascular resistance;univentricular physiology

Main Objective *[detail, max 48 words]*
To determine the safety of Remodulin® in children with PH after Fontan operation

Primary End Point (linked with the main objective)
death, failing Fontan or failed Fontan according to high pulmonary vascular resistance within the first 48 hours after receiving study drug.

Secondary Objectives *[detail, max 160 words]*
To determine the efficiency of Remodulin® to reduce the pulmonary arterial pressure and prevent PH in children after Fontan operation.

Secondary End Points (linked with the secondary objectives)
Change from base line of pulmonary hemodynamic measurements: Pp/Ps reduce >10%

Study Population
Main inclusion and exclusion criteria
Inclusion Criteria:
After Fontan procedure, the criteria should be met:mPAP greater than 15 mmHg;TPG greater than 6 mmHg (exclude the obstruction of cavopulmonary anastomosis)
Exclusion Criteria:
After Fontan surgery :Severe arrhythmia led to low cardiac output;Platelets smaller than 50,000*109/L and obvious bleeding

Design and Conduct of the study
[choose the design + detail max 350 words]
Study Design
Study Type: Interventional
Primary Purpose: Prevention
Study Phase: Phase 3
Intervention Model: Parallel Assignment
Number of Arms: 2
Masking: Single Blind (Subject)
Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Enrollment: 40

If comparison groups:
Experimental group *[detail max 48 words]*
Control group *[detail max 48 words]*
Experimental: Remodulin Injection
Remodulin Injection Dosage:5 ng/kg/min-80ng/kg/min(0.15ml/hr-2.4ml/hr) Frequency: intravenous maintenance increase at a rate of 10ng/kg/min (0.3ml/hr)every 30 minutes Durations:48 hours
Placebo Comparator: Distilled water group
Drug:distilled water Dosage:0.15ml/hr-2.4ml/hr Frequency:increase at a rate of 0.3ml/hr every 30 minutes Durations:48 hours

If Health-Economics Analysis
[tick + detail max 320 words] Others

In the case of a drug trial, phase:
Phase 3

Duration of participation of each patient
[3 digits + days / months / years]
2days
Anticipated Duration of Recruitment (DUR)
[2 digits, in months]
24months
Total number of scheduled patients /observations to be recruited (NP)
[3 digits + Justification of sample size max 80 words]
40

Number of patients / observations to be recruited / month / centre
[2 digits + justification if more than 2 patients/month/centre]

Expected number of patients eligible in the centres
[Table : {Name ; Surname ; Town ; Country ; Expected recruitment/month ; Total}]
*Town:*Shanghai
*Country:*China
*Expected recruitment/month:*2/month
*Total:*40

Participation of a research network
[Detail max 32 words]

Participation of industry
[Detail max 64 words]

Other aspects to insure the feasibility of the project
[Detail max 64 words]

Expected patient or public health benefit
[Detail max 320 words]
Reduce the pulmonary arterial pressure and prevent PH in children after Fontan operation,and improve prognosis.

REFERENCES

Please join a maximum of 5 articles that justify the project in the national / international context.

APPROXIMATE LEVEL OF FUNDING REQUIRED

[en k euros]

KEY WORDS

EXPERTS COMMENTS *[quote]* AND CORRESPONDING ANSWERS[1]

[max 320 words]

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[1] To complete if the project has been previously submitted to a DGOS call for proposals