Observational study for CardioCel

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26419

Source
Nationaal Trial Register

Health condition

Patients requiring repair of valves and annulus and cardiac septal defects including atrial septal defects, ventricular septal defects and atrioventricular defects.

Sponsors and support

Primary sponsor: Admedus Regen Pty Ltd
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

The primary endpoints of the Registry Program are:

• Occurrence of device related safety events, including unexpected or rare events

• Device performance, as documented by interpretation of echocardiography:

o Desired haemodynamics achieved

o Patch dehiscence

o Patch thickening

o Patch retraction

The secondary endpoint of the Registry Program is user satisfaction as evaluated during implantation surgery by the surgeon.

Secondary outcome

NA

Study description

Background summary

The CardioCel Registry Program provides Admedus Regen Pty Ltd

with an opportunity to collect prospective and retrospective, real-world product usage and safety data on patients treated with

CardioCel post-CE Mark. This information serves to formulate and

sustain sound safety, scientific, clinical, quality, reimbursement,

and marketing objectives.

Study objective

There is no formal statistical hypothesis to be tested in this Registry program.

Study design

NA

Intervention

NA

Contacts

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Eligibility criteria

Inclusion criteria

Patients requiring repair of valves and annulus and cardiac septal defects including atrial septal defects, ventricular septal defects and atrioventricular defects. The majority of participating subjects will be paediatrics, since the indication concerns congenital cardiac defects.

Exclusion criteria

This Registry Program does not focus on patients with injured myocardial tissue.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-04-2017
Enrollment:	200
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6263
NTR-old	NTR6437
Other	46/17 S - EC van de Technical University Munich : CC-06 - Admedus Regen Pty Ltd

Study results