

Clinical trials of cell-based therapies for coronary artery disease in all type of patients

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1 cellular therapy

| Trial | Treatments | Patients | Trials design and methods |
|--|--|--|---------------------------------|
| Skeletal Myoblast Transplantation vs placebo | | | |
| Genzyme SMC00202 <i>ongoing</i> [NCT00102128] n=NA follow-up: | Cultured Autologous Skeletal Myoblast Transplantation versus placebo | patient with prior myocardial infarction and referred for CABG | Parallel groups double blind |

References

Genzyme SMC00202, :

2 gene therapy

| Trial | Treatments | Patients | Trials design and methods |
|---|---|--|---------------------------|
| VEGF gene transfer vs control | | | |
| REVASC (Stewart) , 2006 n=NA follow-up: | AdVEGF121 gene transfer with epicardial injection at minithoracotomy versus control | patients with severe angina due to coronary artery disease and no conventional options for revascularization | open |
| fibroblast growth factor gene vs placebo | | | |
| AGENT 3 and 4 pooled n=NA follow-up: | - | - | |
| AGENT-1 (Grines) , 2002 n=NA follow-up: | - | - | |
| AGENT-2 (Grines) , 2003 n=NA follow-up: | - | - | |

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| Trial | Treatments | Patients | Trials design and methods |
|--|--|--|---------------------------------|
| AGENT-3 [NCT00346437] n=NA follow-up: | Ad5FGF-4 (replication deficient, E1A/E1Bdeleted, human adenovirus serotype 5 with human FGF-4 gene insert: alferminogene tadenovec versus placebo | - | |
| AGENT-4 [NCT00185263] n=NA follow-up: | Ad5FGF-4 (replication deficient, E1A/E1Bdeleted, human adenovirus serotype 5 with human FGF-4 gene insert: alferminogene tadenovec versus placebo | - | |
| AWARE [NCT00438867] n=NA follow-up: | intracoronary infusion of Ad5FGF-4 versus placebo | Female Patients With Stable Angina Pectoris Who Are Not Candidates for Revascularization | double blind |
| gene therapy vs placebo | | | |
| EUROINJECT-ONE (Gyngysi) , 2005 n=NA follow-up: | percutaneously via NOGA-Myostar injectionsof plasmid encoding plasmid human (ph)VEGF-A(165) versus placebo | patients with chronic myocardial ischemia | double blind |
| NCT00090714 <i>ongoing</i> [NCT00090714] n=NA follow-up: | recombinant plasmid DNA [pVGL1(VEGF2)] gene therapy versus placebo | patients with severe Angina Pectoris | Parallel groups double blind |

References

REVASC (Stewart), 2006:
AGENT 3 and 4 pooled, 0:
AGENT-1 (Grines), 2002:
AGENT-2 (Grines), 2003:
AGENT-3, 0:
AGENT-4, 0:
AWARE, 0:
EUROINJECT-ONE (Gyngysi), 2005:
NCT00090714, :

3 growth factor

| Trial | Treatments | Patients | Trials design and methods |
|--|------------|----------|---------------------------|
| fibroblast growth factor vs placebo | | | |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|--|---|----------------------------------|
| FIRST (Simons) , 2002 n=NA follow-up: 90 days | Single-bolus intracoronary administration of fibroblast growth factor-2 (FGF2) versus placebo | patients with coronary artery disease | double blind |
| GCSF Granulocyte-Colony Stimulating Factor vs placebo | | | |
| Seiler ongoing [NCT00886509] n=NA follow-up: 6 months | Subcutaneous Administration of Pegylated Granulocyte-Colony Stimulating Factor versus placebo | patients with stable coronary artery disease treatable by PCI | Parallel groups double blind |
| vascular endothelial growth factor vs placebo | | | |
| VIVA (Henry) , 2003 n=NA follow-up: 12 days | intracoronary and intravenous infusions of recombinant human vascular endothelial growth factor protein (rhVEGF) versus placebo | patients with stable exertional angina, unsuitable for standard revascularization | double blind |
| VEGF vs placebo | | | |
| EMAT ongoing [NCT00134433] n=NA follow-up: | growth factor (VEGF) angiogenesis along the diffusely diseased, non-directly bypassed LAD segment at a dose of 2 mg versus palcebo | patients undergoing surgical perivascular angiogenic therapy | Factorial plan double blind |

3

References

FIRST (Simons), 2002:

Seiler, :

VIVA (Henry), 2003:

EMAT, :

4 stem cells

| Trial | Treatments | Patients | Trials design and methods |
|---|--|--|--|
| autologous bone marrowderived mononuclear cells vs placebo | | | |
| Ramshorst , 2009 [ISRCTN58194927] n=25/25 follow-up: 6 months | intramyocardial injection of 100 x 10(6) autologous bone marrow-derived mononuclear cells versus placebo | patients with chronic myocardial ischemia | Parallel groups double blind Netherlands |
| CD34+ cells vs placebo | | | |
| Losordo , 2011 [NCT00300053] n=167 follow-up: 6 months | intramyocardial injection of autologous CD34+ cells versus placebo | patients with refractory angina who have exhausted all other treatment options | Parallel groups double-blind |

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| Trial | Treatments | Patients | Trials design and methods |
|--|---|---|--|
| mesenchymal stem cells vs placebo | | | |
| Kumar <i>ongoing</i> [NCT00883727] n=NA follow-up: 6 months | Intravenous ex Vivo Cultured Adult Allogenic Mesenchymal Stem Cells versus placebo | in patients with ST elevated acute myocardial infarction (STEMI) | Parallel groups double blind India |
| stem cells CD34+ vs placebo | | | |
| Losordo , 2007 [NCT00081913] n=NA follow-up: | Injection of Autologous CD34-Positive Cells versus placebo | Patientswith Canadian Cardiovascular Society class 3 or 4 angina who were undergoing optimal medical treatment and who were not candidates for mechanical revascularization | Parallel groups double blind |

References

Ramshorst, 2009:

Losordo, 2011:

Kumar, :

Losordo, 2007:

5 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

TrialResults-center is non-profit and self-funded.