

OSIRIS-403

Principal Investigator:

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Sub-Investigator:

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Sponsor:

Osiris Therapeutics, Inc.

Study Purpose:

A Phase II, Multi-center, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of PROCHYMAL® (Ex Vivo Cultured Adult Human Mesenchymal Stem Cells) Intravenous Infusion Following Acute Myocardial Infarction

Objective:

The standard of care treatment for acute myocardial infarction (AMI) usually includes immediate perfusion, optimal pain relief, oxygen, aspirin or other anti-coagulants, Beta-Blockers, nitrates and Ace-inhibitors. However, because salvaging the viable myocardium is dependent on early reperfusion, only a minority of patients will reach the hospital within the time-window for myocardial rescue. Thus, even if the patient manages their tobacco use, hypertension, lipid levels, diabetes, weight and exercise, many patients will go on to develop Congestive Heart Failure (CHF). Though the medical management for CHF may improve symptoms and slow disease progression, such treatment cannot restore a functioning myocardium. A therapy that could improve the myocardial remodeling process and reduce the incidence or severity of CHF following acute MI would provide a significant benefit. The characteristics and biologic activity of Prochymal®, along with a good safety profile in human trials to date, suggest that Prochymal® may be a good candidate for addressing this unmet medical need.

Inclusion Criteria:

- Male or female between 21 and 85 years old
- First heart attack within 7 days
- Baseline LVEF 30-45%

Exclusion Criteria:

- Previous heart attack
- Pacemaker or other device
- Pregnant, breast-feeding, or intends to become pregnant during the study

OSIRIS-403

- Allergy to cow or pig derived products
- Evidence of active malignancy or prior history of active malignancy
- Major surgical procedure or major trauma within the past 14 days
- Autoimmune disease (e.g., Lupus, Multiple Sclerosis)
- Any medical condition, which in the opinion of the Investigator, renders participation unsuitable

Status:

Active enrollment

If you have any questions, please feel free to contact the coordinators, and they will be happy to answer any questions you have regarding this study.