UNKNOWN STATUS

A Study to Evaluate the Safety and Pharmacokinetics of RadProtect® in Healthy Volunteers

ClinicalTrials.gov ID NCT02587442

Sponsor Original BioMedicals Co. Ltd.

Information provided by Original BioMedicals Co. Ltd. (Responsible Party)

Last Update Posted 2015-10-27

Study Details Tab

Study Overview

Brief Summary

This is a Phase 1, non-randomized, sequential-cohort, dose escalation, open-label study designed to evaluate the safety and tolerability of RadProtect® in healthy volunteers. This study is to be conducted at two clinical centers and in conformity with Good Clinical Practice (GCP).

Official Title

A Phase I Study to Evaluate the Safety and Pharmacokinetics of RadProtect® in Healthy Volunteers

Conditions

Acute Radiation Syndrome

Intervention / Treatment

- Drug: RadProtect®

Other Study ID Numbers

- OBM-A01-H001

Study Start

2015-10

Primary Completion (Estimated)

2016-03

Study Completion

Enrollment (Estimated)

27

Study Type

Interventional

Phase

Phase 1

Resource links provided by the National Library of Medicine

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Acute Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/6544/acute-graft-versus-host-disease)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Study Contact

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Study Contact Backup

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Maryland Locations

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Recruiting
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Principal Investigator: Mohamed Al-Ibrahim

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study-basics/learn-about-studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Each subject must be willing and able to provide written informed consent for the study
- Healthy volunteer subjects of both genders, aged 18-64 years old, and any race/ethnicity
- Subjects with normal blood pressure (between ranges of 120-140/60-80 mmHg) at screening and baseline
- Subjects with a body mass index (BMI) 18-30 kg/m2
- Men or woman of childbearing potential using adequate contraception (oral contraceptives, intrauterine device or barrier method of contraception in conjunction with spermicidal jelly, or surgically sterile) during screening, while receiving the investigational drug, and for 60 days after stopping the investigational drug
- Female subjects of childbearing potential must have a negative urine pregnancy test at screening
- Subjects with physiological examination and laboratory values within normal limits (CBC/differential, blood chemistry, iron, Total Iron Binding Capacity (TIBC), urinalysis, ECG and vital signs)
- Subjects with the ability to comprehend and complete the telephone visits, screening, and site visits
- Subjects must be able to adhere to dose and visit schedules
- Subjects who agree to abstain from taking unauthorized medications or supplements or participating in any other clinical trial or experimental treatment during this trial.

Exclusion Criteria:

- Subjects with any allergic reaction or sensitivity to glutamate acid, polyethylene glycol, or any component of the test article product
- Subjects who consume > five alcoholic beverages per week
- Subjects who are pregnant or lactating
- Subjects who have blood (or urine) levels outside the normal range for any hepatic, renal, hematologic, lipid or coagulation parameters measured.
- Subjects on Hormone Replacement Therapy within the past three months
- Subjects in any other clinical trial or experimental treatment in the past three months
- Subjects with a history of diabetes (Type 1 or Type 2 diabetes mellitus) or other endocrine disorders, hypertension, hypotension or systolic blood pressure below 80 mmHg, prior cerebrovascular accident or seizure disorder, cardiovascular, hepatic or renal disease, active cancer, hematologic disorder, thromboembolic disease, or HIV infection.

Ages Eligible for Study

18 Years to 64 Years (Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

Yes

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Safety and tolerability profile including the dose limiting toxicity (DLT) of RadProtect® intravenous injection to healthy volunteers.	DLT is defined as a subject's symptom worse than a Grade 2, with the exception of the value for Total Protein and Cholesterol that should be determined by the investigator as these values may be affected by diet and there may be no discomfort or immediate risk for subjects. During the telephone visits on Day 3, 14+2, and 28+2 after injection, the study coordinator will confirm the subject's status, report to the investigators, and will schedule extra hospital visits if necessary.	Day 0~ Day 28

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Pharmacokinetic (PK) parameters	PK samples will be obtained from the arm opposite the side of infusion. A total of	Day 0 ~ Day 1

of RadProtect® by analyzing subjects' serum for free WR-1065 at different time points.	approximately 4 mL of whole blood per collection time point per subject will be collected for the PK analysis. There will be a total of 10 or 16 times during this study when the sampling times for PK analysis will take place (this will depend on the dosing group).	(24 hours after dosing)

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Original BioMedicals Co. Ltd.

Collaborators

No information provided

Investigators

No information provided

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

- Chen CH, Kuo ML, Wang JL, Liao WC, Chang LC, Chan LP, Lin J. CCM-AMI, a Polyethylene Glycol Micelle with Amifostine, as an Acute Radiation Syndrome Protectant in C57BL/6 Mice. Health Phys. 2015 Sep;109(3):242-8. doi: 10.1097/HP.0000000000000326. (https://pubmed.ncbi.nlm.nih.gov/26222219)

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2015-10-26

First Submitted that Met QC Criteria
2015-10-26

First Posted (Estimated)
2015-10-27

Study Record Updates

Last Update Submitted that met QC Criteria
2015-10-26

Last Update Posted (Estimated)
2015-10-27

Last Verified
2015-10

More Information

Terms related to this study

Keywords Provided by Original BioMedicals Co. Ltd.

Acute Radiation Syndrome
ARS
Amifostine
Radio-protectants

Additional Relevant MeSH Terms

Wounds and Injuries

Radiation Injuries

Acute Radiation Syndrome