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Allogenic Stem Cell Therapy in Patients With Acute Burn

This study is currently recruiting participants.

Verified November 2012 by Shenzhen Beike Bio-Technology Co., Ltd.

Sponsor:
Shenzhen Beike Bio-Technology Co., Ltd.

Collaborator:
The Second Affiliated Hospital of Kunming Medical University

Information provided by (Responsible Party):
Shenzhen Beike Bio-Technology Co., Ltd.

ClinicalTrials.gov Identifier:
NCT01443689

First received: September 27, 2011
Last updated: November 26, 2012
Last verified: November 2012
History of Changes

Full Text View | **Tabular View** | **No Study Results Posted** | Disclaimer | How to Read a Study Record

Purpose

Burn **trauma**,especially extensive ones, remains a life-threatening local and general inflammatory condition destroying the skin and underlying **tissues**, and resulting in serious sequelae. Remarkable progress has been achieved during last 30 years , stem cell therapy plays an important role in this progress. Human umbilical **cord** mesenchymal stem cells (hUCMSCs) and human **cord blood** mononuclear cells (hCBMNCs) have been shown to have the ability to modulate the immune response and enhance angiogenesis, suggesting the novel and promising therapeutic strategy for burn. In this study, the safety and efficacy of hUCMSCs and hCBMNCs transplantation will be evaluated in patients with acute burn.

Condition	Intervention	Phase
Burns	Biological: human umbilical **cord** mesenchymal stem cells Biological: human **cord blood** mononuclear cells and human umbilical **cord** mesenchymal stem cells Drug: Conventional therapy	Phase 1 Phase 2

Study Type: Interventional
Study Design: Allocation: Non-Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label

Primary Purpose: Treatment

Official Title: A Phase I/Π Study of Human **Cord Blood** Mononuclear Cells and Human Umbilical **Cord** Mesenchymal Stem Cells Transplantation in Patients With Acute Burn

Resource links provided by NLM:

MedlinePlus related topics: Burns

U.S. FDA Resources

Further study details as provided by Shenzhen Beike Bio-Technology Co., Ltd.:

Primary Outcome Measures:

- The ratio of wound contraction and re-epithelialisation [Time Frame: 6 months after treatment] [Designated as safety issue: No]
- Complete healing time for investigated burn area [Time Frame: 6 months after treatment] [Designated as safety issue: No]
- Vancouver Scar Scale [Time Frame: 6 months after treatment] [Designated as safety issue: No]

Secondary Outcome Measures:

- Incidence of infections and bleedings in burn wounds [Time Frame: 6 months after treatment]] [Designated as safety issue: No]
- Engraftment assessment: Vitality of the graft [Time Frame: 6 months after treatment]] [Designated as safety issue: No]
- McGill pain Questionnaire [Time Frame: 6 months after treatment] [Designated as safety issue: No]
- Incidence of Adverse Events and Serious Adverse Events [Time Frame: 6 months after treatment] [Designated as safety issue: Yes]

Estimated Enrollment:	20
Study Start Date:	July 2011
Estimated Study Completion Date:	July 2013
Estimated Primary Completion Date:	March 2013 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Group1 :Conventional plus hUCMSCs treatment Participants will be given conventional therapy plus human **cord** mesenchymal stem cells transplantation with a 6 months follow-up.	Biological: human umbilical **cord** mesenchymal stem cells Participants will be given conventional therapy plus hUCMSCs transplantation.
Experimental: Group 2: Conventional plus hCBMNCs and hUCMSCs therapy Participants will be given conventional therapy plus combination of hCBMNCs together with hUCMSCs transplantation with a 6 months follow-up.	Biological: human **cord blood** mononuclear cells and human umbilical **cord** mesenchymal stem cells Participants will be given conventional therapy plus and hCBMNCs and hUCMSCs transplantation.
Active Comparator: Group 3:Conventional therapy Participants will be given conventional therapy only with a 6 months follow-up.	Drug: Conventional therapy Participants will be given conventional therapy only.

Detailed Description:

To investigate the safety and efficacy of human cord blood mononuclear cells and human umbilical cord mesenchymal stem cells transplantation in patients of Acute, Moderate-Severe, Full-thickness burn.

Eligibility

Ages Eligible for Study:	18 Years to 65 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Between age 18- 65 years, both gender.
- Diagnosed with Acute, Moderate-Severe, full-thickness burn:

Burn occurring within the 72 hours prior to administration. TBSA 20-55%, third degree wounds surface area < 19 % ;

- Willing to sign the Informed Consent Form.

Exclusion Criteria:

- All other burns except thermal origin.
- Chronically malnourished, poor medical condition or shock
- Systemic inflammatory response syndrome (SIRS) or septicopyemia
- Moderate-severe inhalation injury airways to lung
- HIV+
- Autoimmune disease, e.g. lupus erythematosus, multiple sclerosis.
- Severe pulmonary and hematological disease, malignancy or hypo-immunity.
- Currently undertaking other treatment that may affect the safety/efficacy of stem cells.
- Pregnancy or lactation
- Enrollment in other trials in the last 3 months.
- Other criteria the investigator consider improper for inclusion.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01443689

Contacts

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Locations

China, Yunnan

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The Second Affiliated Hospital of Kunming Medical University

More Information

No publications provided

Responsible Party:	Shenzhen Beike Bio-Technology Co., Ltd.
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Health Authority:	China: Ministry of Health

Keywords provided by Shenzhen Beike Bio-Technology Co., Ltd.:
Extensive Burn
Human **Cord Blood** Mononuclear Cells
Human Umbilical **Cord** Mesenchymal Stem Cells

Additional relevant MeSH terms:
Burns
Wounds and **Injuries**

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