

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Treating aplasia cutis with amniotic membrane in newborn Infants

Protocol summary

Study aim

Aplasia Cutis Treatment with Amniotic Membrane

Design

Single-Arm Clinical Trial on 5 patients with diagnosis of Aplasia Cutis Congenita

Settings and conduct

The untreated or uncontrolled Cutis Aplasia could lead to infection, water-electrolyte imbalance, hypothermia and death in infants. The use of Amniotic Membrane as an Allograft could act a crucial roll in its treatment. After hospitalization of Infants in Children's Medical Center, the amniotic membrane will be used weekly under observation of physician until epithelization as wound cover after wound assessment and treatment of infection and necrotic tissue (if exists) .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Newborn Infants with Aplasia Cutis Congenita more than 1 centimeter Exclusion criteria: Any other life threatening anomalies and suffering from Dystrophic Epidermolysis Bolusa

Intervention groups

Amniotic Membrane dressing (Sinacell Co.) as Allograft every 7 days, dressing size selection based on wound dimensions, until epithelization

Main outcome variables

Epithelization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191024045229N1**

Registration date: **2019-12-28, 1398/10/07**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-28, 1398/10/07**

Update count: **0**

Registration date

2019-12-28, 1398/10/07

Registrant information

Name

Kayvan Mirnia

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6642 8998

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-21, 1398/09/30

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Treating aplasia cutis with amniotic membrane in newborn Infants

Public title

Amniotic Membrane Effect in Aplasia Cutis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Newborn Infants suffered from Aplasia Cutis Congenita

Exclusion criteria:

Presence of Life Threatening Anomaly Suffering from Dystrophic Epidermolysis Bulosa Aplasia Cutis Congenita less than 1 centimeter

Age

From **1 day** old to **90 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 5

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Qods St., Keshavarz Blvd.

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Tehran

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Postal code

1417653761

Approval date

2019-10-07, 1398/07/15

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.529

Health conditions studied**1****Description of health condition studied**

Aplasia Cutis Congenita

ICD-10 code

Q82.8

ICD-10 code description

Other specified congenital malformations of skin

Primary outcomes**1****Description**

Epithelization

Timepoint

Before intervention and weekly until complete skin formation

Method of measurement

Clinical Assessment

Secondary outcomes**1****Description**

Death

Timepoint

During the Study

Method of measurement

Electrocardiography

2**Description**

Sepsis

Timepoint

Baseline (before the intervention) and weekly

Method of measurement

Blood Test and Clinical prove

3**Description**

Hospitalization Period

Timepoint

During the Study

Method of measurement

Documents Assessment

4**Description**

Electrolytes Abnormality

Timepoint

Baseline (before the intervention) and weekly if necessary

Method of measurement

Blood Test

5**Description**

Systemic Antibiotic Therapy

Timepoint

Baseline (before the intervention) and weekly if necessary

Method of measurement

Prescription duration

6**Description**

Scar Forming after Wound Treatment

Timepoint

After Wound Healing

Method of measurement

'Vancouver Scare Scale' questionnaire

7

Description

Wound Erythema

Timepoint

Baseline (before the intervention) and weekly

Method of measurement

Clinical Assessment

8

Description

Wound Infection

Timepoint

Baseline (before the intervention) and weekly if necessary

Method of measurement

Wound Exuda Culturing

9

Description

Frequency of Amniotic membrane changing

Timepoint

During the Study

Method of measurement

Document Assessment

10

Description

Time to Epithelization

Timepoint

Baseline (before the intervention) and weekly

Method of measurement

Logging the epithelization time via clinical assessment

Intervention groups

1

Description

Intervention group: Amniotic Membrane dressing (Sinacell Co.) as Allograft every 7 days, dressing size selection based on wound dimensions, until epithelization

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Center

Full name of responsible person

Kayvan Mirnia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy of Tehran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research deputy of Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Malihe Kadivar

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Neonatology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Kayvan Mirnia

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Medical doctor

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Medical Pharmacy

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available