Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Epidermolisis 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
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Iran (Islamic Republic of)
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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 Epidermolisis 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.
City
Tehran
Province
Tehran
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
Street address
Gharib St., Keshavarz Blvd
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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
Mohammad Ali Sahraian
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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
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Person responsible for updating data

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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