

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation Efficacy of Amniotic Membrane in Treatment of Extravasation in Infants

Protocol summary

Study aim

Determination of Amniotic Membrane in the treatment of Extravasation in infants

Design

Single-arm clinical trial on 4 patients with wound due to Extravasation, a pilot study

Settings and conduct

The untreated or uncontrolled wound due to extravasation could lead to tissue disorders, necrosis, scar, movement limitation and even amputation in Infants. The use of Amniotic Membrane as an Allograft could act a crucial role in its treatment. After hospitalization of patient 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: Infants who suffered wound higher than stage 2, due to Estravasation. Exclusion Criteria: Infants with congenital skin disorders.

Intervention groups

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

Main outcome variables

Time to epithelization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191024045229N2**

Registration date: **2020-02-02, 1398/11/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-02, 1398/11/13**

Update count: **0**

Registration date

2020-02-02, 1398/11/13

Registrant information

Name

Kayvan Mirnia

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-20, 1398/10/30

Expected recruitment end date

2020-07-20, 1399/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation Efficacy of Amniotic Membrane in Treatment of Extravasation in Infants

Public title

Amniotic Membrane in Extravasation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infant with diagnosis of wound due to drug leak

Exclusion criteria:

Wound with stage 1 or 2 Congenital skin disorders

Age

From **1 day** old to **3 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **4**

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.1398.530

Health conditions studied

1

Description of health condition studied

Extravasation Leak

ICD-10 code

T80.818A

ICD-10 code description

Extravasation of other vesicant agent, initial encounter

Primary outcomes

1

Description

Time to epithelization

Timepoint

Before intervention and weekly until epithelization

Method of measurement

Logging the time (day)

Secondary outcomes

1

Description

Scar Forming after Wound Treatment

Timepoint

After Wound Healing

Method of measurement

'Vancouver Scare Scale' questionnaire

2

Description

Hospitalization Period

Timepoint

During the Study until epithelization

Method of measurement

Documents Assessment

3

Description

Sepsis

Timepoint

Before the initiation of intervention and then weekly

Method of measurement

Clinical assessment and blood sampling

Intervention groups

1

Description

Intervention group: 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

Mohammad Ali Sahraian

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vcr@tums.ac.ir

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

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Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Amini Pouya

Position

Non-faculty Pharm. D

Latest degree

Medical doctor

Other areas of specialty/work

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