Autologous Skin Substitute for leg ulcers.

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A prospective, multicenter, randomised controlled phase II study in which patients with therapy resistant (arterio-) venous leg ulcers are treated in an outpatient setting with an autologous cultured human living skin substitute (Tiscover®: test...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23091

Bron
Nationaal Trial Register

Aandoening

chronic (arterio) venous leg ulcers

Ondersteuning

Primaire sponsor: Free University medical center (VUmc)
Overige ondersteuning: A-SKIN Nederland BV
ZONmw translational research
Agentschap NL

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Efficacy (Time to heal: time point of healing, Number and percentage of closed ulcers at week 12 and 26);
2. Ulcer size: Percentage of reduction;
3. Safety.

Toelichting onderzoek

Achtergrond van het onderzoek

A prospective, multicenter, randomised controlled phase II study in which patients with therapy resistant (arterio-) venous leg ulcers are treated in an outpatient setting with an autologous cultured human living skin substitute (Tiscover®: test group) or with Acellular donor dermis (AS210: control group) to determine the safety and relative efficacy of both products.

49 adults (> 18 years) admitted for outpatient wound care in the VU medical center or nearby collaborating centers with (arterio-) venous leg ulcers not responding to standard treatment will be selected. A therapy resistant leg ulcer is defined as an ulcer existing for 12 weeks or longer without or with minimal improvement, despite optimal treatment. During a pre-inclusion evaluation period of 4 weeks based on 4 weeks protocol treatment or historical data determination chronicity of ulcer to ensure there is no intention to heal (i.e. size reduction is < 15%) takes place. Patients with leg ulcers between 1 – 40 cm2 will be selected for inclusion.

Intervention:

The test group (33 pts) and control group (AS210 will receive 2 applications (week 0 and week 1). will receive 2 applications of Tiscover® at week 0.

Doel van het onderzoek

A prospective, multicenter, randomised controlled phase II study in which patients with therapy resistant (arterio-) venous leg ulcers are treated in an outpatient setting with an autologous cultured human living skin substitute (Tiscover®: test group) or with Acellular donor dermis (AS210: control group) to determine the safety and relative efficacy of both products.

Onderzoeksopzet

12 weeks, 26 weeks, 3 and 6 months follow up.

Onderzoeksproduct en/of interventie

Application of skin substitute or acellulair dermis at week 0 and week 1.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Presence of confirmed venous, arterio-venous ulcer;

2. Patients age over 18 years and under age of 90 years;

3. Ulcer duration over 12 weeks and less than 5 years consecutively;

4. <15% ulcer size reduction in 4 weeks prior to inclusion;

5. Ulcer is between 1-40 cm2 in size;

6. ABPI ≥ 0.7 and < 1.2;

7. Ulcer depth < 1 cm;

8. Mobile, at least able to walk with medical walker, and able to return for required

treatments and study evaluations;

9. (Legally) capable to give informed consent;

10. Able to understand and comply with requirements of study protocol.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Ulcer chronicity < 12 weeks;

2. >15% increase of ulcer size in 4 weeks prior to inclusion or confirmed by historical data (patient status);

3. Presence of deep vein trombosis or contra indication for compression therapy;

4. Severe co-morbidity reducing life expectance to < 1 year;

5. Use of oral corticosteroids and/or cytostatics >20 mg/per day;

6. Allergies to Gentamycin (which is used in the tissue media), Clindamycin or Ciprofloxacin, or the used local wound treatments;

7. Severe infection of ulcer, active cellulitis, osteomyelitis;

8. Expected non-compliance with compression therapy, protocol treatment or no informed consent;

9. Severe malnutrition;

10. Uncontrolled diabetes mellitus, HbA1c > 12% (108 mmol/mol);

11. Anaemia Hb <6 mmol/l;

12. Current participation in another clinical trial, prior participation in another trial in 3 months.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2012
Aantal proefpersonen:	49
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-05-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40033
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3274
NTR-old	NTR3427
CCMO	NL32502.000.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Register	ID
OMON	NL-OMON40033

Resultaten

Samenvatting resultaten

Wound healing in venous ulcers; mechanisms, approach and modern developments. Gibbs S, van den Hoogenband HM, de Boer EM.
Ned Tijdschr Geneeskd. 2007 Mar 17;151(11):635-40. Review. Dutch.
Autologous full-thickness skin substitute for healing chronic wounds.Gibbs S, van den Hoogenband HM, Kirtschig G, Richters CD, Spiekstra SW, Breetveld M, Scheper RJ, de Boer EM. Br J Dermatol. 2006 Aug;155(2):267-74.