Efficacy of Verapamil/ Verapamil-Kenacort injection versus Kenacort injection in Scar Treatment

Published: 28-10-2014
Last updated: 21-04-2024

Scar volume and POSAS score will be measured in the Verapamil group, these will be compared to the scar volume and POSAS score in the Kenacort+Verapamil group and the Kenacort group. In addition, complications/ adverse effects will be reported.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON43777

Source
ToetsingOnline

Brief title
Verapamil vs Kenacort injection in Scar Treatment

Condition

- Epidermal and dermal conditions
- Skin and subcutaneous tissue therapeutic procedures

Synonym
hypertrophic/keloid scar, raised scar

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: hypertrophic scar, keloid, kenacort, verapamil

Outcome measures

Primary outcome

The main study endpoint is the difference in volume of the hypertrophic or keloid scar, measured by a three-dimensional volume measurement technique using the Vectra XT 3D imaging system. (Canfield Imaging Systems, Fairfield, N.J.)

Secondary outcome

The first secondary study endpoint is difference in POSAS score. The POSAS consists of two parts: a Patient Scale and an Observer Scale. The other secondary study endpoint is the occurrence of any complications/side effects.

Study description

Background summary

Hypertrophic and keloid scars often lead to major cosmetic and functional consequences. For this reason, effective treatment is important in clinical practice. Corticosteroid injections are the mainstay of treatment for excessive scarring.
Verapamil injections were recently introduced and showed promising results. Our hypothesis is that Verapamil has a similar efficacy and fewer adverse effects compared to corticosteroids.

Study objective

Scar volume and POSAS score will be measured in the Verapamil group, these will be compared to the scar volume and POSAS score in the Kenacort+Verapamil group and the Kenacort group. In addition, complications/ adverse effects will be reported.

Study design

A randomized, controlled pilot study with a follow up period of one year will

be performed. Patients will be allocated to one of three groups: Verapamil, Kenacort+Verapamil, Kenacort. Observers of the volume and POSAS and patients will be blinded.

Intervention

Patients will receive a series of 3 injections of the medication that they are allocated to. These injections will be given at the beginning of the study (week 0), week 1 and week 3.

Study burden and risks

After the series of injections, patients need to visit the outpatient clinic 4 times for the assessments and possible additional treatment. This means a total of 7 appointments in 1 year. A visit will not take more than 15 minutes; they have to fill out a questionnaire and a 3D photo will be taken. The close follow up regarding objective and subjective outcome of treatment in the studied subjects is likely to be beneficial.
There won*t be any major risks attached to participation. Kenacort is widely accepted and used for treatment of hypertrophic and keloid scars. Verapamil is used in daily practice in the Maastricht University Medical Center, with good experiences so far.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Hypertrophic scar
Definition: Excessive overgrowth of dense collagen tissue, often red, pink, or purple in appearance, at the site of a healed skin defect. It resembles a keloid but is usually temporary, most often regresses without treatment, and remains confined to the site of injury.(http://medical-dictionary.thefreedictionary.com/hypertrophic+scarring)
- Keloid scar
Definition: A nodular, firm, often linear mass of hypertrophic thickish scar tissue, consisting of irregularly distributed bands of collagen; occurs in the dermis, usually after trauma, surgery, burn, or a severe cutaneous disease. (http://medicaldictionary.thefreedictionary.com/keloid)
- >= 18 years old

Exclusion criteria

- Hypertrophic or keloid scar on ear and scalp
- Hypertrophic or keloid scar with a treatment history of radio-, brachy- or cryotherapy, or steroid- or other intralesional therapies in the passed year
- Allergy or intolerance to corticosteroids or Verapamil
- Pregnancy

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-02-2016
Enrollment:	45
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Kenalog-40
Generic name:	Triamcinolone Acetonide
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Verapamil Hydrochloride
Generic name:	Verapamil Hydrochloride
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	28-10-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	12-02-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2014-003216-37-NL
CCMO	NL50902.068.14