An Assessment of the Prevalence of Psoriasis in Patients with Hepatitis C

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This single-center investigation will assess the prevalence of psoriasis in a population of patients with hepatitis C and compare the prevalence in those patients receiving pegylated interferon-* therapy to those not receiving pegylated interferon...

Ethical review	Approved WMO
Status	Pending
Health condition type	Cornification and dystrophic skin disorders
Study type	Observational non invasive

Summary

ID

NL-OMON34745

Source
ToetsingOnline

Brief title
An Assessment of the Prevalence of Psoriasis in Patients with Hepatitis C

Condition

- Cornification and dystrophic skin disorders

Synonym
chronic skin disease with increased keratinization, psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: het wordt niet gefinancierd

Intervention

Keyword: hepatitis C, observational, prevalence, psoriasis

Outcome measures

Primary outcome

Efficacy outcome measurement will include evaluation of the skin for either the presence or absence of psoriasis, through the psoriasis area severity index (PASI) . Additionally, patients will be evaluated for total Body Surface Area (BSA) involved. An average palm represents 1% of the BSA.

Secondary outcome

Not applicable

Study description

Background summary

Psoriasis is a chronic, immune-mediated disease characterized by erythematous, scaly plaques on the skin. It is estimated that psoriasis affects 2% of the general population. Psoriasis is thought to be an autoimmune disorder in which the body attacks a currently unknown antigen in the skin. Most patients have a genetic predisposition to develop psoriasis, and triggering factors include infections, medications, or physical trauma to the skin.

Interferon is a naturally existing glycoprotein in the body. It possesses immune modulating properties and is commonly used as a treatment for many tumors and infections, including hepatitis C. Patients on interferon therapy are at risk for developing autoimmune conditions and exacerbation of pre-existing conditions. Psoriasis is among these conditions, and has been reported both to be exacerbated and newly develop in patients on interferon therapy. Psoriasis often improves when the interferon treatment is stopped.

Study objective

This single-center investigation will assess the prevalence of psoriasis in a population of patients with hepatitis C and compare the prevalence in those patients receiving pegylated interferon-* therapy to those not receiving

pegylated interferon-* treatments.

Study design

A goal of 80 consecutive hepatitis C patients,with and without pegylated interferon-* treatment, will be evaluated by the department of dermatology at the AMC directly after the visit with the hepatologist. These patients will sign informed consent.. They will be given full body skin examinations to evaluate for the presence of psoriasis.
The pegylated interferon-* must had been given for at least one dose, within the last 6 months, as we would expect to see psoriasis persist in that period of time. The dose, type and duration of pegylated interferon-* treatment will be documented, as well as data about a history of diagnosed psoriasis and treatment.
A detailed medical history will be taken and a full-body skin examination will be performed, with special emphasis on typical sites of involvement with psoriasis, such as elbows and knees, looking for erythema with squamae. The examination of the skin will be standardized. The observer was blinded as to whether or not the patients were treated with pegylated interferon-*.
If the skin examination reveals the presence of any kind of psoriasis, photographs will be taken of the affected area, as a record . In case of doubt, review by an second dermatologist will be performed. If the second dermatologist thinks it is questionable too, patients will be scored as not having psoriasis in the analysis.
The study procedures will include a review of the charts of the patients in the clinic to evaluate the number of patients with the diagnosis of psoriasis, as well as which of these patients are on pegylated interferon-* therapy.

Study burden and risks

There are no risks associated with patient participation in this study since no study drugs will be given and no histology will be applied.
The data will give a contribution to the knowledge of developing or exacerbation of psoriasis in treatment with pegylated interferon-*.

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

1.Age 18 years or greater
2.Subjects must have a previous diagnosis of Hepatitis C. This would include all patients with a positive serology for Hepatitis C.
3.Patients in the treatment group should be treated for at least one dose, within the last 6 months, with pegylated interferon-*.

Exclusion criteria

1.Subjects younger than 18 years old
2.Subjects with any skin disease, disease state, or physical condition that would impair evaluation of the skin, for example not able to undress or stand up.

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2010
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL31109.018.10