Management of psoriasis and risk and severity of COVID-19 infection in systemic, biologic and topical treatment for psoriasis during the COVID-19 pandemic: an epidemiological cohort study

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Evaluate the point-prevalence, relative risk and severity of COVID-19 infections in psoriasis patients treated with immunosuppressive biologicals or conventional systemic immunosuppressive therapies as compared to topical treatments. Furthermore, we...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON51144

Source
ToetsingOnline

Brief title
PsoCovid

Condition

- Viral infectious disorders
- Epidermal and dermal conditions

Synonym
Psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: Bravis Ziekenhuis
Source(s) of monetary or material Support: deze Investigator Initiated Trial krijgt sponsoring van Novartis,Novartis

Intervention

Keyword: biologics, Covid-19, Psoriasis, Risk

Outcome measures

Primary outcome

The point-prevalence of COVID-19 infection in the 3 treatment groups

Risk ratios and confounder corrected odds ratio for treatment with biologics or conventional systemics vs. topical therapies regarding the risk of COVID-infections.

Secondary outcome

Proportion of severe COVID-19 infection in infected patients in the 3 treatment groups

Patient satisfaction with their management by their dermatologist with a visual analogue scale.

Patient satisfaction with different modes of teleconsultations with a visual analogue scale.

Psoriasis disease activity change during this period on a with a visual analogue scale.

Proportions of patients who stayed on treatment, changed treatment or stopped

treatment due to Covid-19 infection (fear) with or without consent of their

treating dermatologist.

Study description

Background summary

Psoriasis is a chronic inflammatory skin disease which affects approximately 2% of the population. In recent years an increasing amount of patients are being treated for psoriasis with biological immunosuppressive agents such as anti-TNF-alpha, anti IL12/23, Anti-IL17 and recently anti-IL23 antibodies as opposed to treatment with conventional systemic immunosuppressive agents such as methotrexate, ciclosporin and fumaric acid. Currently, it is still unknown whether treatment with these immunosuppressive medications have to be stopped or continued during the Covid-19 pandemic.

Recently a couple of studies and case reports described Covid-19 incidence in dermatology, especially psoriasis patients treated with biologicals, and indicated few hospitalizations1,2,3. However, the patients included in these studies were only patients that were admitted to the hospital and tested for Covid-19 infections because of their symptoms. Another Italian study contacted all their psoriasis patients in their outpatient service, but also here, only a few patients were actually tested.4 As only hospitalized psoriasis patients were tested, it is still unclear the use of these immunosuppressive agents influenced the infection rate or the severity of Covid-19 disease in psoriasis patients. A recent study on seroprevalence of COVID-19 in a small biological treated psoriasis cohort without controls seems to suggest that the use if these medications is not associated with severe covid-19 infection.
Evidence on the actual infection rate, proven bij PCR or serological tests, is scant and therefore the observation of just a few severe infections in this group might also be explained by a lower infection rate due to different behavior of psoriasis patients compared to the healthy population. It was recently reported that psoriasis patients showed more risk-mitigating behavior, which may lower the risk of being infected in this group5. It is therefore not clear whether the use of immunosuppressive drugs for psoriasis results in an increase in Covid-19 infections and/or more severe course compared to the non-systemic treated psoriasis patients. An increase in infection-rate and severity could relate to the immunosuppressive effects of systemic anti-psoriatic therapies, like methotrexate or biologics.

In patients using systemic immunosuppressive therapies, a decrease in disease severity is also a possibility due to the suppression of parts of the cytokine storm associated with Covid-19 infections6,7. Several cytokines have been found

to play a role in this storm: IL-6, IL-10, IL12 and TNF. And the use of anti-TNF alpha and other biologics and immunosuppressive drugs have been suggested as possible treatments for severe Covid-19 infections.
At this moment there is clinical support of therapeutical effect of IL-6 inhibitor tocilizumab12,13, and in several cases of anti-TNF-alpha: etanercept14 and infliximab15 in people suffering from Covid-19 infection. For anti-IL-17 biologicals it*s not clear, some suggest it could be used as a treatment for Covid-1916, but there are also some case reports with patients who had severe Covid-19 disease while treated with anti-IL-17 biologicals.
Without an effective treatment, and current state of viral mutations with new emerging Covid-19 strain it will be very important to know whether patients on immunosuppressive medications are at increased risk of getting Covid-19 and whether they are more prone to severe Covid-19 infections or whether biologics can even have a protective effect by e.g. suppressing the cytokine storm implicated in Covid-19 infections. However, this requires insight in the actual seroprevalence of COVID-infections and information on the number of severe infections in this group. Due to this lack of knowledge, psoriasis patients have not been advised uniformly how to manage their psoriasis and their anti-psoriatic treatment. Patients have therefore sometimes even stopped their treatment (with or without their doctors consent) due to concerns of increased susceptibility for serious Covid-19 infections. This could potentially result in an increased psoriasis disease activity and worsened quality of life.

Study objective

Evaluate the point-prevalence, relative risk and severity of COVID-19 infections in psoriasis patients treated with immunosuppressive biologicals or conventional systemic immunosuppressive therapies as compared to topical treatments.
Furthermore, we would like to evaluate the management of these psoriasis patients during the recent pandemic. How did hospitals inform these patients on how to use their immunosuppressive medication in these times (continue or discontinue)? Did patient perform self-quarantine or not? Did patients experience an increase in psoriatic disease activity? How did hospitals stay in contact with these patients (outclinic visits, phone calls, teleconsultations (Apps/chat/video consultations). How was this change in care perceived by the patients? Are there lessons to be learned for the next wave(s) of the pandemic or for psoriasis care in general? andemic

Study design

epidemiological cohort study

Study burden and risks

Burden: patient has to make time to answer the one time questionnaire and go to

a local blood withdrawal lab to give 10 ml blood., the blood withdrawal can sometimes be combined with other planned bloodwork
Risk: common blood withdrawal risks
Benefit: knowledge of having had (sub)clinical COVID-19 infection.

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

* Subject is able to sign the informed consent form.
* Age of 18 years or older
* Subject is currently being treated for psoriasis with:
o Conventional systemic immunosuppressive therapy (CSIT) including: methotrexate, cyclosporin A or fumaric acid. Concomitant topical therapy is allowed.

o Biological immunosuppressive therapy (BIT) including, but not limited to: anti IL-17a, anti IL-23 or anti TNF-alpha biological agents. Concomitant topical therapy is allowed. Combination with low dose MTX is allowed
o Topical therapy (TT) including corticosteroids, anthralin, calcipotriene, topical vitamin D derivatives, retinoids, urea and medicated shampoos

Exclusion criteria

* Subject is being treated with immunosuppressive therapy for any indication other than psoriasis
* Subject is incapacitated or otherwise incapable of participating in the study.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2021
Enrollment:	1500
Type:	Actual

Ethics review

Approved WMO

Date:	15-03-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	08-04-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL76575.091.21