# Dose response and safety study of topical methotrexate for the treatment of fingernail psoriasis

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
11/04/2008	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
24/04/2008	Completed	Results
Last Edited	Condition category	[] Individual participant data
26/02/2019	Skin and Connective Tissue Diseases	<ul><li>Record updated in last year</li></ul>

## Plain English summary of protocol

Not provided at time of registration

# Contact information

### Type(s)

Scientific

### Contact name

Prof Neil McHugh

### Contact details

Royal National Hospital for Rheumatic Diseases Upper Borough Walls Bath United Kingdom BA1 1RL

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

NCT00666354

Secondary identifying numbers

06-003

# Study information

### Scientific Title

Phase IIB dose response and safety study of topical formulations of methotrexate (MQX-5902, MQX-5904 and MQX-5906) in the treatment of fingernail psoriasis

### **Study objectives**

The purpose of this clinical study is to compare, in a controlled fashion, the response to three concentrations of methotrexate in novel topical formulations in the treatment of subjects with psoriasis of the fingernails. Such a determination will be used as the basis for evidence of efficacy and safety of these formulations as a therapeutic treatment for fingernail psoriasis.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

South West Research Ethics Committee, 17/04/2007, ref: 07/MRE06/25

### Study design

Multi-centre, randomised, double-blind, efficacy and safety study

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Psoriasis of the fingernail

### **Interventions**

1. Active comparator one:

Drug: methotrexate (other names: MQX-5906)

Dosing: 0.01 g of topical amphimatrix containing 0.05% methotrexate per affected nail and adjacent skin folds applied daily for three months

2. Active comparator two:

Drug: methotrexate (other names: MQX-5902)

Dosing: 0.01 g of topical amphimatrix containing 0.25% methotrexate per affected nail and adjacent skin folds applied daily for three months

3. Active comparator three:

Drug: methotrexate (other names: MQX-5904)

Dosing: 0.01 g of topical amphimatrix containing 1.0% methotrexate per affected nail and adjacent skin folds applied daily for three months

Total duration of follow-up is 1 month.

### Intervention Type

Drug

### Phase

Phase II/III

### Drug/device/biological/vaccine name(s)

Topical formulations of methotrexate (MQX-5902, MQX-5904 and MQX-5906)

### Primary outcome measure

- 1. Evaluate improvements in the appearance of the target fingernail, utilising photography for imaging and independent photograph evaluators, measured monthly for 4 months
- 2. Assess safety, i.e., the frequency and severity of adverse events associated with MQX-5902, MQX-5904 and MQX-5906 in the treatment of patients with fingernail psoriasis, measured monthly for 5 months

### Secondary outcome measures

Secondary endpoints will include:

- 1. The improvement in the appearance of the control fingernail as determined by independent evaluators
- 2. The improvement of the target fingernail as measured by the investigator using the mNAPSI (a modification of the Nail Psoriasis Severity Index)
- 3. A comparison of the improvement of the mNAPSI of the target and control fingernails
- 4. Information on the relative changes in nail psoriasis severity of the other affected fingernails
- 5. A comparison of nail growth of the target and control fingernails as determined from nail notch movement measured on nail photographs

Secondary outcomes measured monthly for 4 months.

## Overall study start date

01/10/2007

### Completion date

01/01/2009

# Eligibility

### Key inclusion criteria

- 1. Diagnosed moderate fingernail psoriasis of at least two fingernails
- 2. Stable and unchanged psoriasis therapies for two months and must not have received methotrexate for three months prior to screening
- 3. Female patients who are not five years post menopausal or surgically sterile must use appropriate birth control for specified time periods and have negative pregnancy tests
- 4. 18 75 years of age and either sex

### Participant type(s)

Patient

### Age group

Adult

### Lower age limit

18 Years

### Upper age limit

75 Years

### Sex

Both

### Target number of participants

83

### Key exclusion criteria

- 1. Target or control fingernails that are thicker than 2 mm, abnormal or infected (bacterial or fungal)
- 2. Patients with immunosuppression, human immunodeficiency virus (HIV), or neuropathies of the hand
- 3. Use of any methotrexate preparation, any topical anti-psoriatic medications or ultraviolet treatment within two months of study visit one
- 4. Use of more that one two-week course of oral corticosteroid therapy or one injection during three months prior to the screening visit
- 5. Use of manicures or cosmetic nail products during and within seven days of the start of treatment
- 6. Use of any drug known to have potential for toxicity to a major organ during and within 90 days prior to the start of treatment
- 7. Patients who are nursing, pregnant or plan to become pregnant or father a child within the study time frame including within three months of the last dose of study medication

### Date of first enrolment

01/10/2007

### Date of final enrolment

01/01/2009

# Locations

### Countries of recruitment

England

United Kingdom

### Study participating centre

### Royal National Hospital for Rheumatic Diseases

Bath United Kingdom BA1 1RL

# Sponsor information

### Organisation

MediQuest Therapeutics, Inc. (USA)

### Sponsor details

22322 20th Ave. S.E. Suite 100 Bothell United States of America 98021 +1 425 398 9580 info@mqti.com

### Sponsor type

Industry

### Website

http://www.mqti.com

# Funder(s)

### Funder type

Industry

### Funder Name

MediQuest Therapeutics, Inc. (USA)

# **Results and Publications**

### Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**Not provided at time of registration