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

Submission date	Recruitment status	[ ] Prospectively registered
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	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00666354

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex

All

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
United Kingdom

England

Study participating centre
Royal National Hospital for Rheumatic Diseases
Bath
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Sponsor information

Organisation
MediQuest Therapeutics, Inc. (USA)

Funder(s)

Funder type
Industry

Funder Name
MediQuest Therapeutics, Inc. (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration