hELP Study Summary Flowchart

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

hELP
systemic therapy
for vulval Erosive
Lichen Planus

Identification of participants

Baseline/screening clinic visit (Visit 1)
Informed consent, eligibility, digital photo

Randomisation (Visit 2)

Medication specific safety assessments prior to start of treatment

Prednisolone + clobetasol propionate 0.05%

Hydroxychloroquine + clobetasol propionate 0.05%

Methotrexate + clobetasol propionate 0.05%

Mycophenolate mofetil + clobetasol propionate 0.05%

Clinic visit (1 months) (Visit 3)
Standard safety monitoring and adherence, titrate medications if indicated

Clinic visit (3 months) (Visit 4)
Standard safety monitoring and adherence, titrate medications if indicated, record assessment parameters

Clinic visit (6 months) (Visit 5)
Primary and secondary outcomes measures including digital photo

Final follow-up contact (12 months from randomisation) (Visit 6)
Contact by telephone, letter, online to assess long term efficacy, check pregnancy status

Treatment phase

Follow-up phase