

Randomized Clinical Trial Comparing the Safety and Efficacy of Rituximab Versus Oral Cyclophosphamide in Severe Forms of Mucous Membrane Pemphigoid

NCT03295383

Status	RECRUITING
Phase	Phase 3
Sponsor	University Hospital, Rouen
Enrollment	130 participants

Key Eligibility Criteria

Inclusion (17)

- Male or female patients aged ≥ 18 years old and ≤ 80 years old with a newly diagnosed or previously diagnosed severe MMP diagnosed according to the International MMP Consensus (Chan 2002) on the following criteria:
 - Clinical features: Blisters or erosions predominantly affecting any or all mucous membranes (oral, nasal, pharyngeal, laryngeal, anal, genital, or esophageal,) with or without clinically observable scarring. Ocular involvement includes conjunctival inflammation, shortening of fornices, symblepharon, ankyloblepharon, entropion, trichiasis and corneal neovascularisation.
 - Patients with skin involvement must not have more than 2 out of the 4 clinical criteria for bullous pemphigoid (BP) proposed by the French group (Vaillant L et al, 1998; Joly P et al. 2004) Direct Immunofluorescence (DIF): Linear deposits of IgG, IgA and/or C3 on the BMZ by DIF of patient's skin or mucous membrane Histology: Sub epithelial blister with or without significant leukocyte infiltrate by standard histology of skin or mucosal lesions, when the skin or mucosal biopsy is possible and appropriate.
 - MMP is defined as "severe" in patients with:
 - Sight-threatening ocular disease, and/or Potentially life-threatening laryngeal, tracheal or oesophageal stenosis, and/or Involvement of a mucosal site where there is a risk of scarring stenosis (larynx, trachea, esophagus, anus, foreskin, vagina...) and/or More than one mucosal site involved and/or Mucosal involvement (including exclusive but severe oral involvement defined as an oral MMP DAI score > 10), and/or Skin involvement, which have not achieved control of disease activity despite a one month treatment with dapsone at the maximum dose tolerated or for patients with sight-threatening ocular disease, and/or potentially life-threatening laryngeal, tracheal or oesophageal stenosis, without previous treatment by dapsone
- ... and 12 more (see full listing online)

Exclusion (40)

- Patient < 18 years old or > 80 years old
 - Non-consenting patient or patient who cannot be followed regularly
 - Patients with only MMP sequelae (stenosis, fibrosis, without inflammation or disease activity)
 - Patients with Brunsting Perry pemphigoid and exclusive skin lesions without mucosal involvement
 - Karnofsky index $< 50\%$ (see Appendix 3)
- ... and 35 more (see full listing online)

Locations (27 total)

CHU Amiens, Amiens, France
CHU Angers, Angers, France
CH Argenteuil, Argenteuil, France
... and 24 more locations

<https://clinicaltrials.gov/study/NCT03295383>

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