MEPODOSE

Efficacité d'une dose réduite de mépolizumab chez les patients avec GEPA cortico-dépendante : une analyse coût-utilité.

(Programme de Recherche Médico-Economique 2024)

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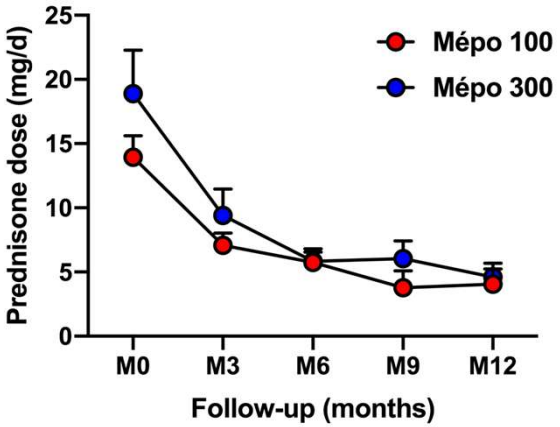
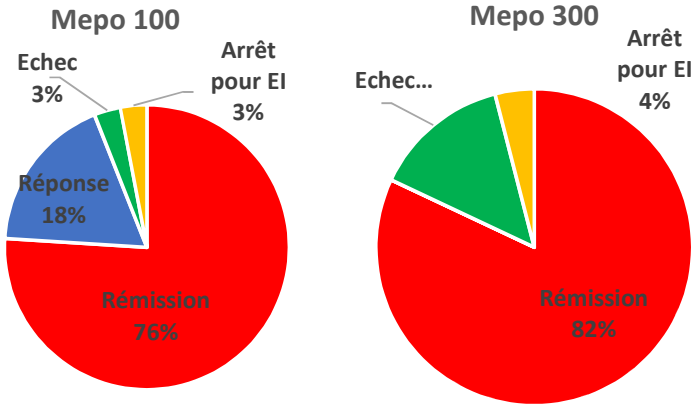
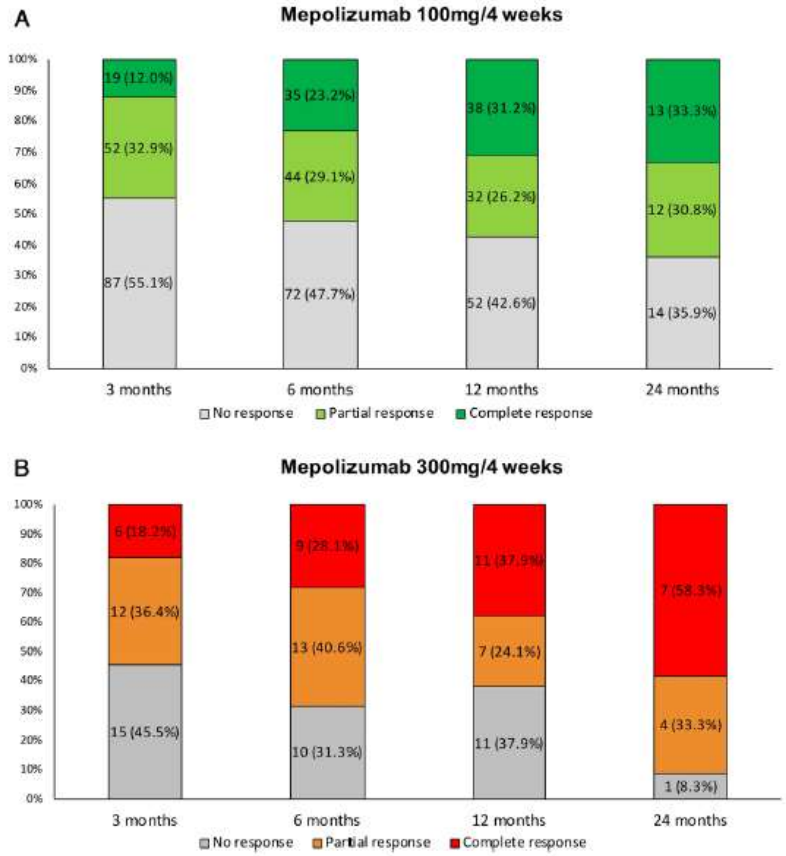
GFEV GROUPE FRANÇAIS D'ÉTUDE DES VASCULARITES

Quelle dose de mépolizumab ?





Canzian, Arthritis Rheum, 2021



"The 2 doses of mepolizumab should be compared in the setting of a controlled trial"

Bettiol, Arthritis Rheum, 2022

Quelle dose de mépolizumab ?

Si efficacité comparable : économie potentielle de 22 000 euros par patient par an pour une durée de ?

Objectifs

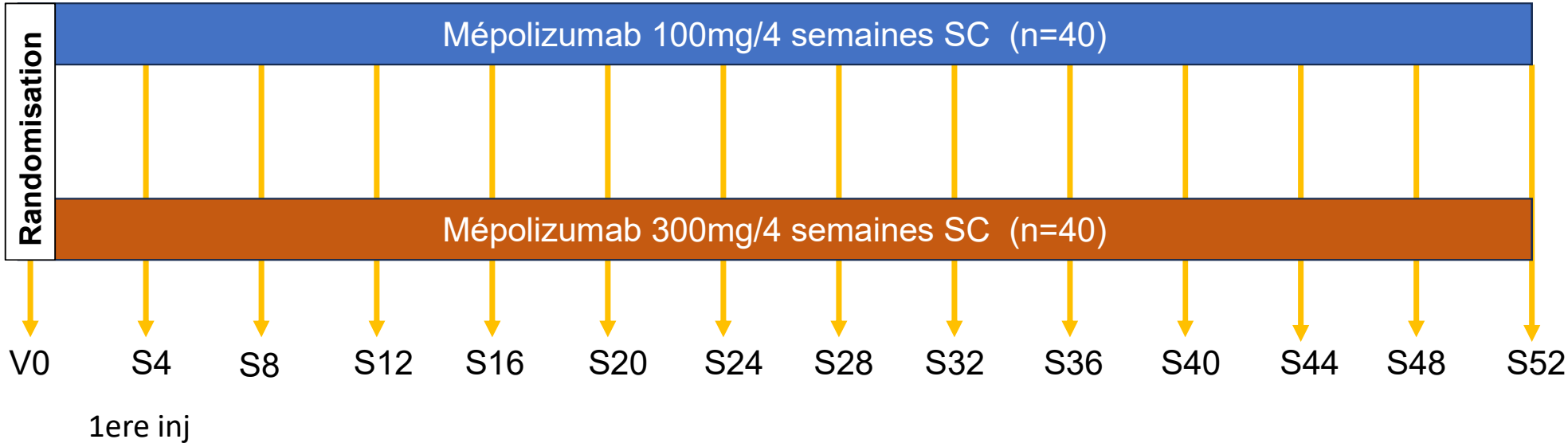
- Evaluer le ratio coût-utilité (les années de vie pondérées par la qualité (QALYs) sont calculées en utilisant le score de qualité de vie liée à la santé du questionnaire EQ5D5L, puis converties en utilité).

- Evaluer le ratio coût-efficacité
- Comparer l'effet des 2 doses sur l'épargne cortisonique (prednisone <4mg/j à 24 semaines sans rechute)
- Evaluer l'effet de la réduction de dose sur le fardeau du traitement

- Contrôle asthme, Polypes, vascularite..
- Sécurité

Méthode

Etude multicentrique, de non infériorité, randomisée, en ouvert.



Pas de stratification sur les éosinophiles à l'inclusion

Critères d'inclusion

i. Patient aged of 18 years or older,

ii. Patients who have documented EGPA diagnosis,

iii. Patients who have a history of relapsing or refractory disease and while receiving a dose of prednisolone (or equivalent) of ≥7.5 mg/day,

iv. Therapy with corticosteroids ≥7.5 mg/day for at least 4 weeks prior to inclusion,

v. Immunosuppressive therapy at stable dose for the 4 weeks prior to baseline,

vi. Patient able to give written informed consent

- Affiliation with a mode of social security

Critères d'exclusion

i. Patients with other vasculitis,

ii. Patients with severe cardiac failure,

iii. Patients with acute or chronic active infections,

iv. Patients with active cancer or recent cancer (<5 years),

v. Pregnant women and lactation,

vi. Patients with EGPA who have already been treated with mepolizumab or benralizumab,

vii. Patients with hypersensitivity to a monoclonal antibody or biologic agent,

viii. Patients suspected not to be observant to the proposed treatments,

- Patients without effective contraception

Informed consent	X		
Randomization	X		
History	X		
Clinical examination	X	X	X
Pregnancy test in women of childbearing potential and request of effective contraception for the duration of the study	X	X (pregnancy test for WOCBP)	X (pregnancy test for WOCBP)
Medical procedures ECG	X		
Birmingham Vasculitis Activity Score (BVAS)	X	X	X
Vasculitis Damage Index (VDI)	X	W28	X
Biological tests: Biochemistry,haematology, urine analysis ANCA	*	X	X
HIV, HBV and HCV serological tests	X (If previous tests > 12 months)		
Imaging tests:chest X-ray, thoracic CT-scan ehocardiography, cardiac MRI	X		
SAQ,EQ-5D-5L and HAQ questionnaires	X	W28	X
ACQ and SNOT-22 questionnaires	X	X	X
Treatment burden questionnaire			
Spirometry	X	W28	X
Dispensation of treatments	Treatment dispensed 10 days after randomization	X	
Compliance	X	X	X
Collection book of prednisone tapering	X	X	
Adverse events		X	X

- Recruitment period: 36 months
- Study participation: 12 months (364 days);
- Total duration: 50,5 months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