MAINTENANCE OF REMISSION USING **E**XTENDED ADMINISTRATION OF **P**REDNISONE IN SYSTEMIC **AN**CA-ASSOCIATED VASCULITIS: THE **MAINEPSAN** STUDY

A PROSPECTIVE, MULTICENTRIC, RANDOMIZED, CONTROLLED, DOUBLE-BLIND TRIAL

JOURNÉE DU GFEV

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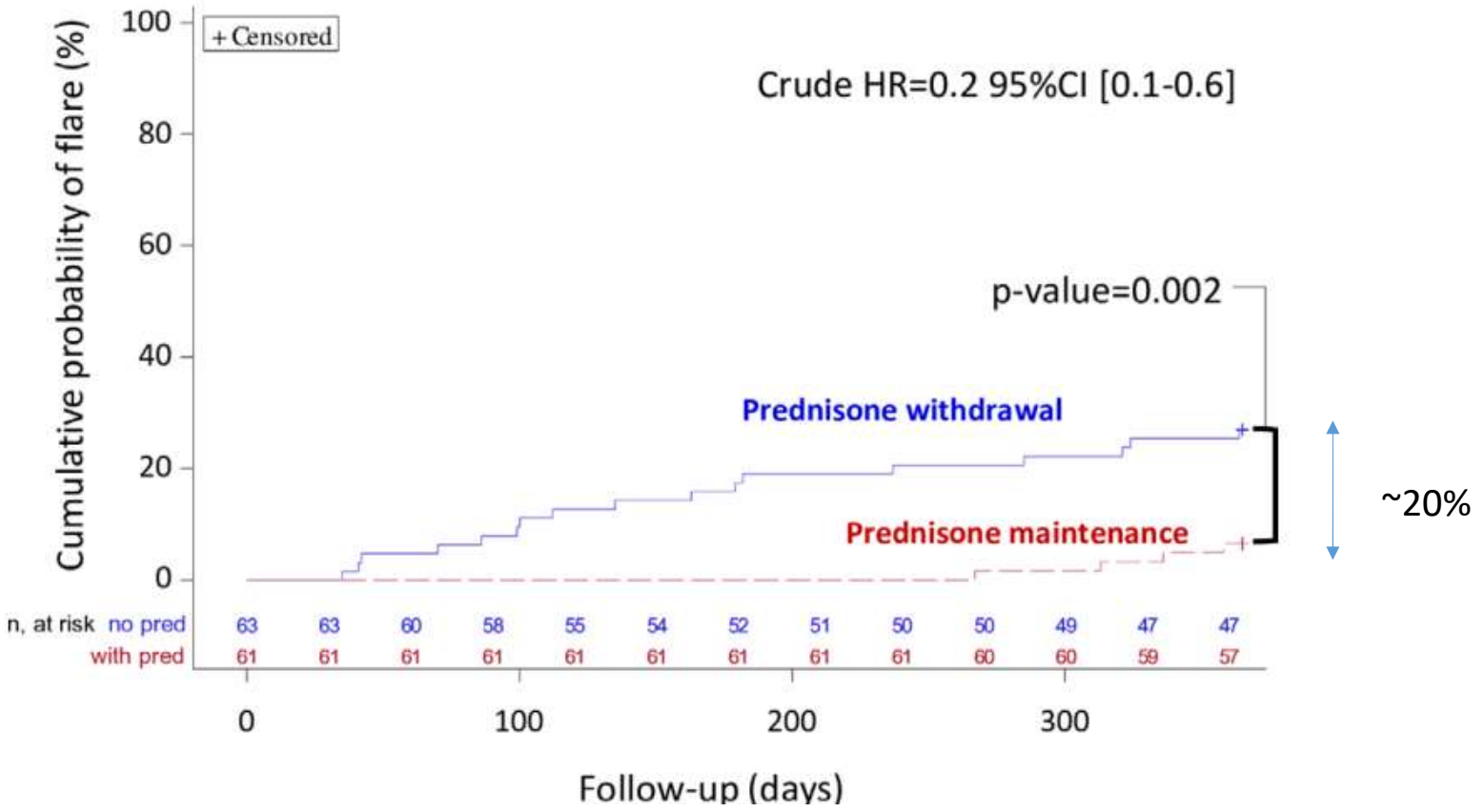
Rationnel

CORTICOLUP



Mathian et al. Withdrawal of low-dose prednisone in SLE patients with a clinically quiescent disease for more than 1 year: a randomised clinical trial. Ann Rheum Dis 2020;79:339–346.

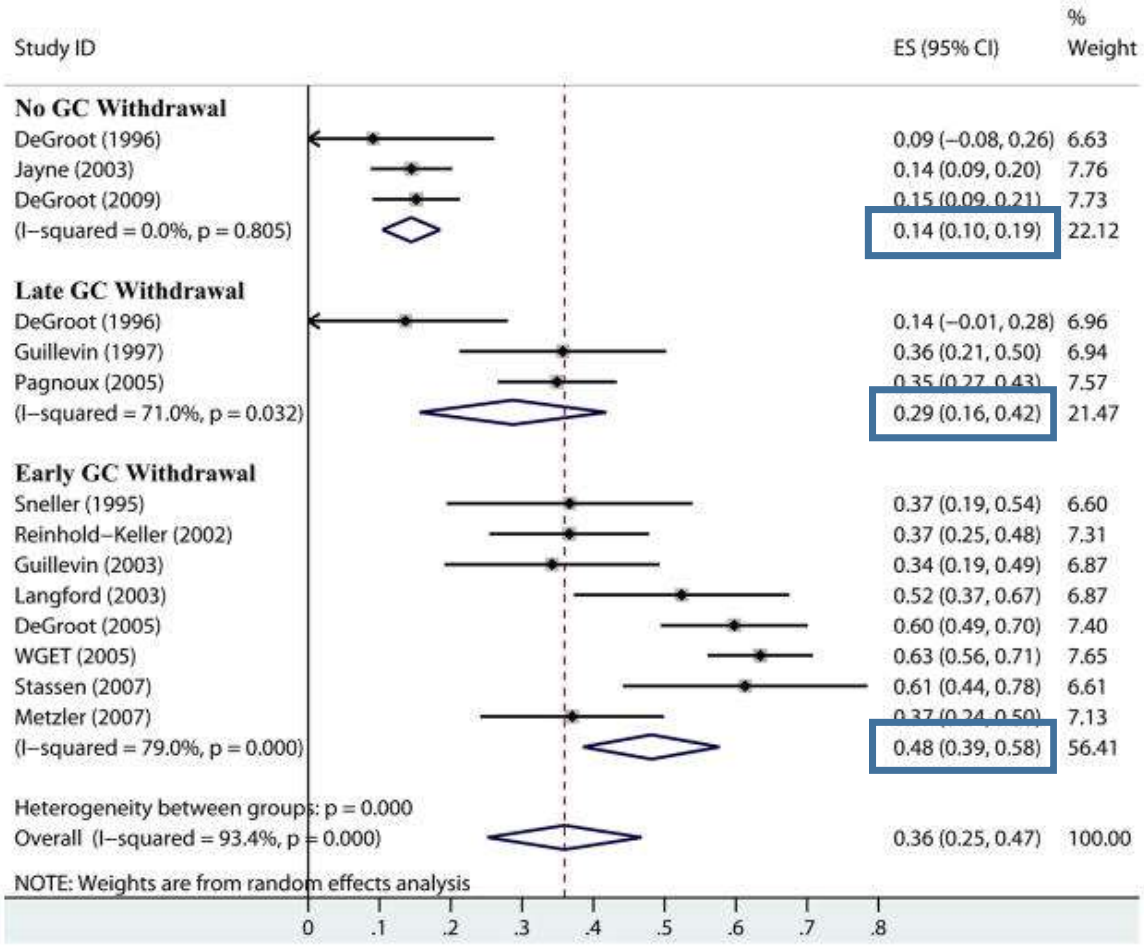
Rationnel

EULAR recommendations for the management of ANCA-associated vasculitis: 2022 update

Since there is little evidence to guide low-dose GC therapy during remission in AAV,[154] duration and dosage need to be individualised on a shared decision basis, taking into account the patient's individual disease course, risk for or presence of GC-related comorbidities and patient preferences. There is lower-quality evidence that GC withdrawal increases relapse risk,[154] but high-quality prospective studies on the role of GC are yet lacking. Regular screening for GC-related comorbidities during continued low-dose GC therapy is recommended according to EULAR recommendations for monitoring adverse events of low-dose GC therapy.[34]

Hellmich B, et al. Ann Rheum Dis 2023;0:1–18. doi:10.1136/ard-2022-223764

Rationnel



- Sevrage : 43% (IC95% 31-52)
- Non sevrage : 14% (IC 95% 10-19)

Walsh et al. The effects of duration of glucocorticoid therapy on relapse rate in anti-neutrophil cytoplasm antibody associated vasculitis: A meta-analysis. Arthritis Care Res (Hoboken). 2010; 62(8): 1166–1173.

Rituximab	Azathioprine	MMF
Scheduled dosing protocol: **1.** 500 mg × 2 at complete remission, and 500 mg at mo 6, 12, and 18 thereafter (MAINRITSAN scheme) OR **2.** 1000 mg infusion after induction of remission, and at mo 4, 8, 12, and 16 after the first infusion (RITAZAREM* scheme)	1.5–2 mg/kg/d at complete remission until 1 yr after diagnosis then decrease by 25 mg every 3 mo	2000 mg/d (divided doses) at complete remission for 2 yr
	Extend azathioprine at complete remission until 4 yr after diagnosis; start at 1.5–2 mg/kg/d for 18–24 mo, then decrease to a dose of 1 mg/kg/d until 4 yr after diagnosis, then taper by 25 mg every 3 mo. Glucocorticoids should also be continued at 5–7.5 mg/d for 2 yr and then slowly reduced by 1 mg every 2 mo	

Figure 14| Immunosuppressive dosing and duration of AAV maintenance therapy. MAINRITSAN, MAINtenance of Remission Using RITuximab in Systemic ANCA-associated Vasculitis; MMF, mycophenolate mofetil; RITAZAREM, Rituximab versus azathioprine as therapy for maintenance of remission for antineutrophil cytoplasm antibody-associated vasculitis (AAV). *RITAZAREM was in relapsing AAV.

KDIGO 2024 Clinical Practice Guideline for the Management of AAV Kidney International 2024 ; 105 (Suppl 3S)

Rationnel

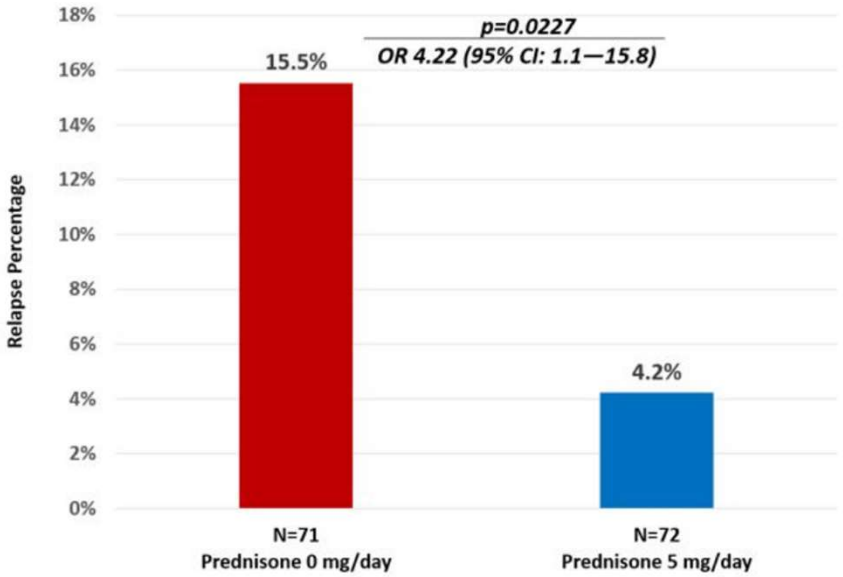
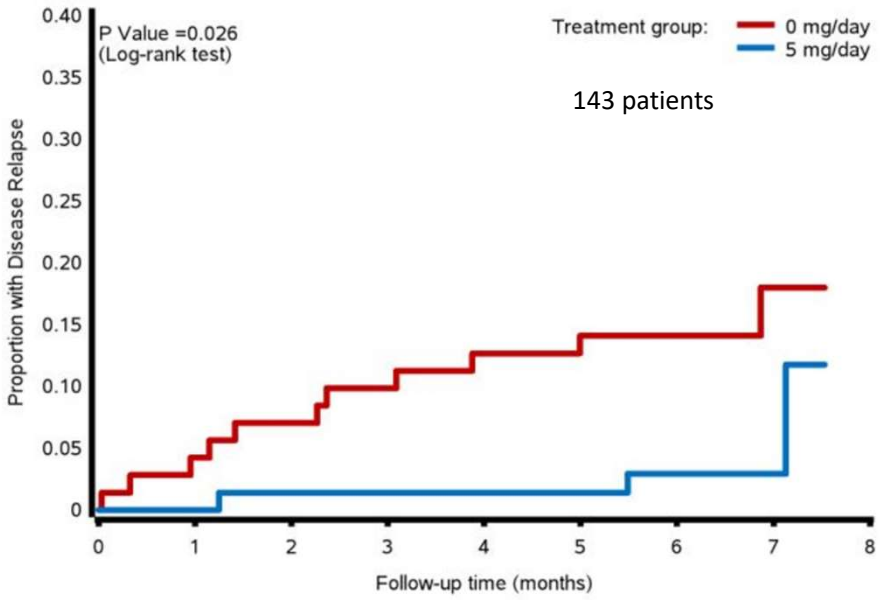


Figure 1: Relapse rates in the TAPIR trial



- Essai en ouvert, GPA
- Traitement de maintenance par RTX : 54%
- Outcome à M6

Merket et al. A Multicenter, Randomized, Controlled Trial to Evaluate the Effects of Low-dose Glucocorticoids Compared to Stopping Glucocorticoids to Maintain Remission of Granulomatosis with Polyangiitis: The TAPIR Trial. Abstract ACR 2024

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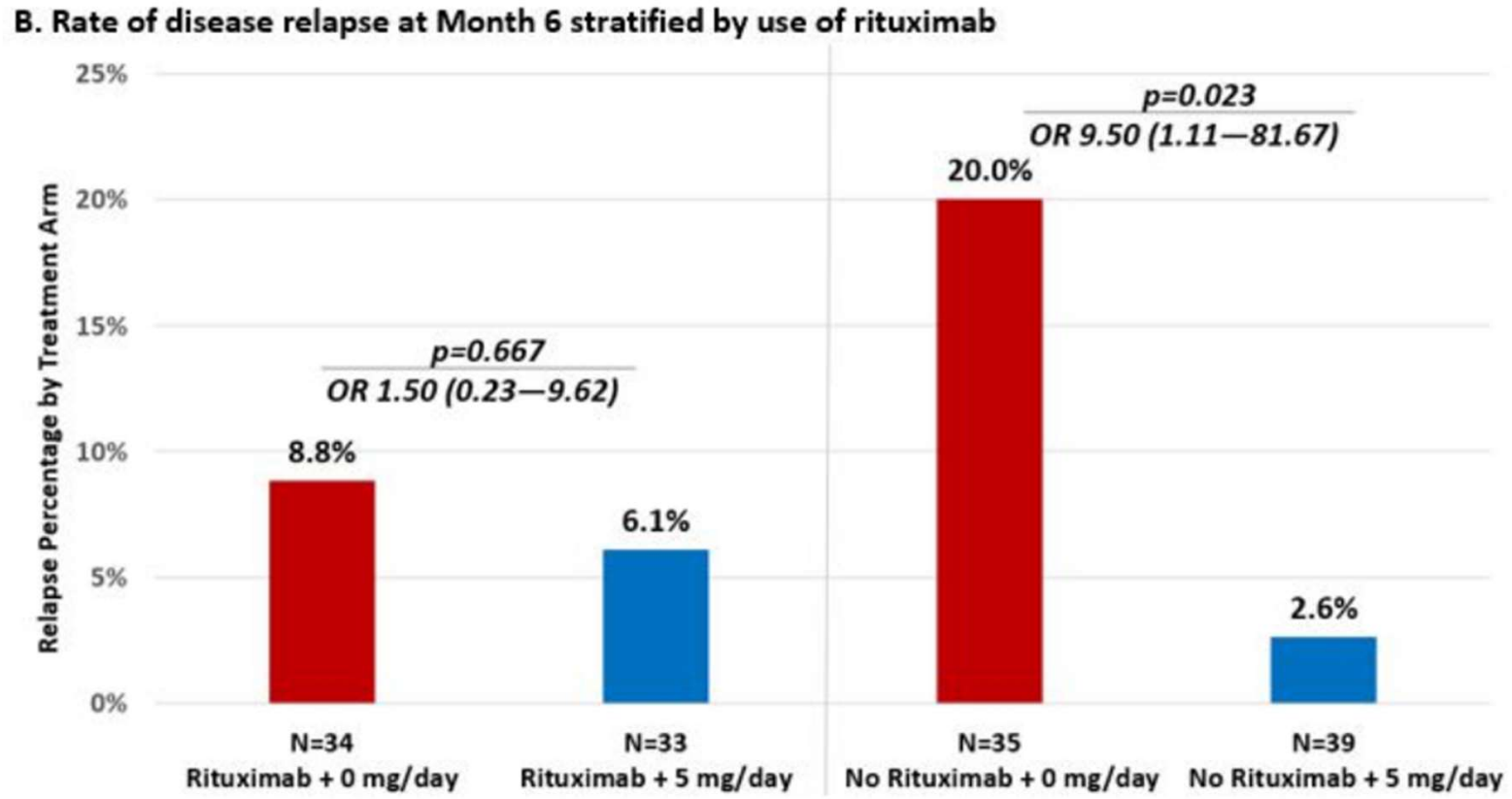


Figure 1: Relapse rates in the TAPIR trial

Merket et al. A Multicenter, Randomized, Controlled Trial to Evaluate the Effects of Low-dose Glucocorticoids Compared to Stopping Glucocorticoids to Maintain Remission of Granulomatosis with Polyangiitis: The TAPIR Trial. Abstract ACR 2024

Objectifs

- Tester la supériorité de la prednisone à faible dose (5 mg) pendant 12 mois vs arrêt sur le maintien de la rémission des patients avec GPA ou MPA

Design

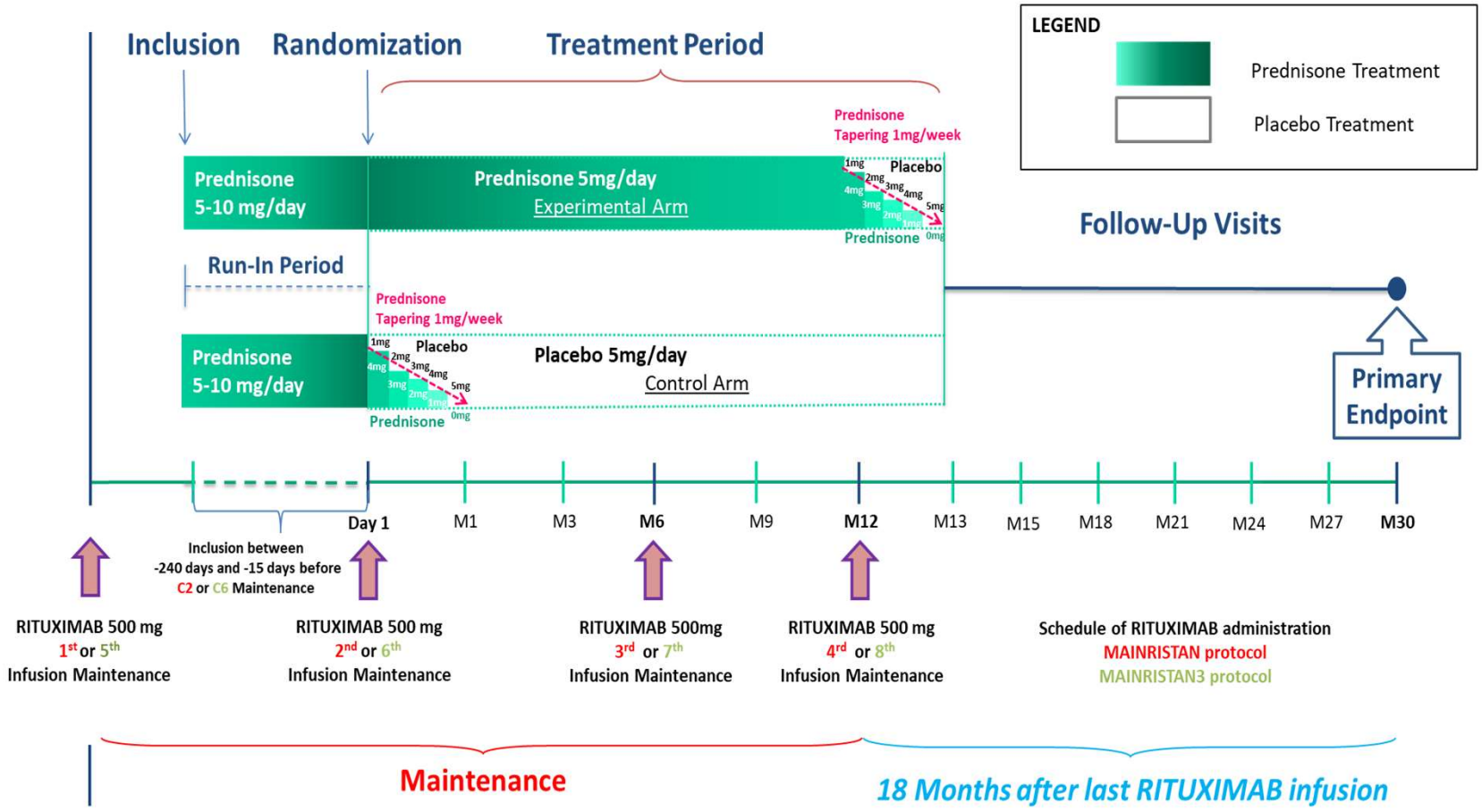
- **Critère de jugement primaire** : Survie sans rechute (BVAS=0) à M30 post-randomisation

- **Critère d'inclusion**
  - PAM ou GPA
  - âge >18 ans
  - Induction par MTX, CYC ou RTX
  - Maintenance par RTX selon schéma MAINRITSAN ou MAINRITSAN3
  - Patients sous 5-10 mg au screening avec BVAS =0 à M12/M36 post-induction

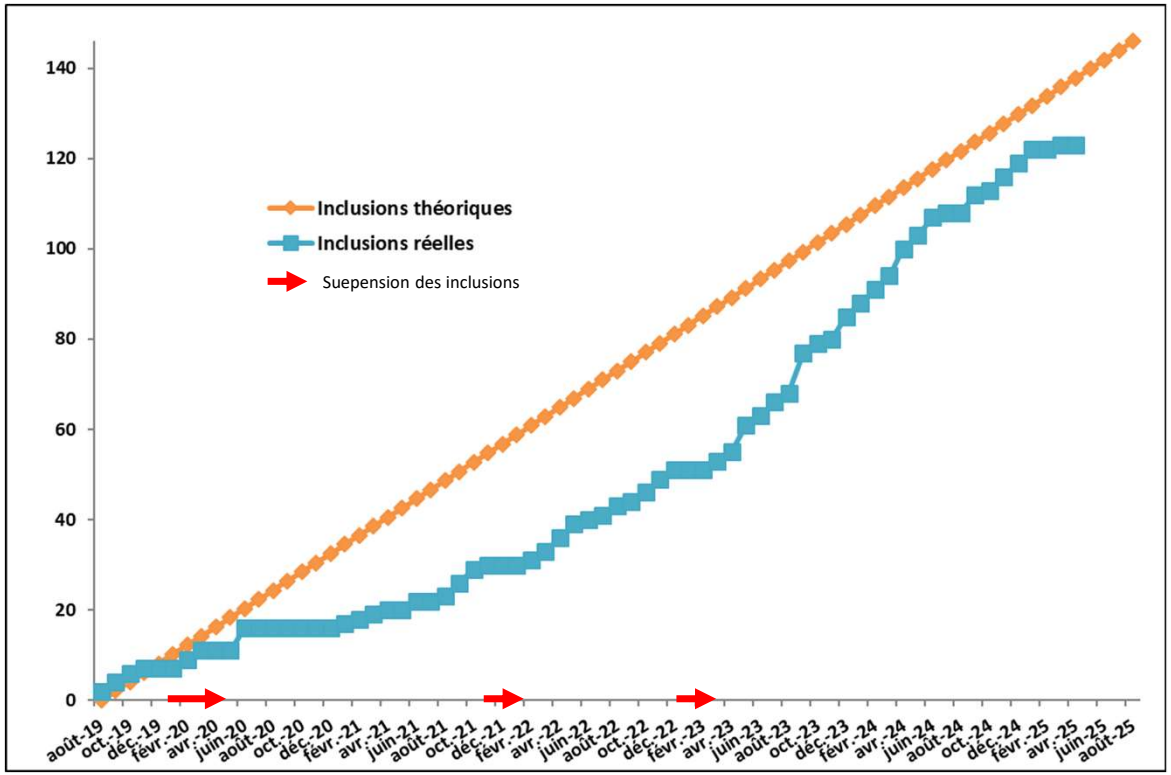
- **Critère d'exclusion**
  - EGPA
  - Infections aigües (incluant Covid-19) + VHC, VHB ou VIH
  - PNN <1500
  - Hypogammaglobulinémie <5 g/L (symptomatique) ou 3 g/L (asymptomatique)
  - **Absence de vaccination Covid-19** selon recommandations

- Analyse en ITT, double-aveugle

STUDY DESIGN



ETAT DES INCLUSIONS



Parution de MAINRITSAN3

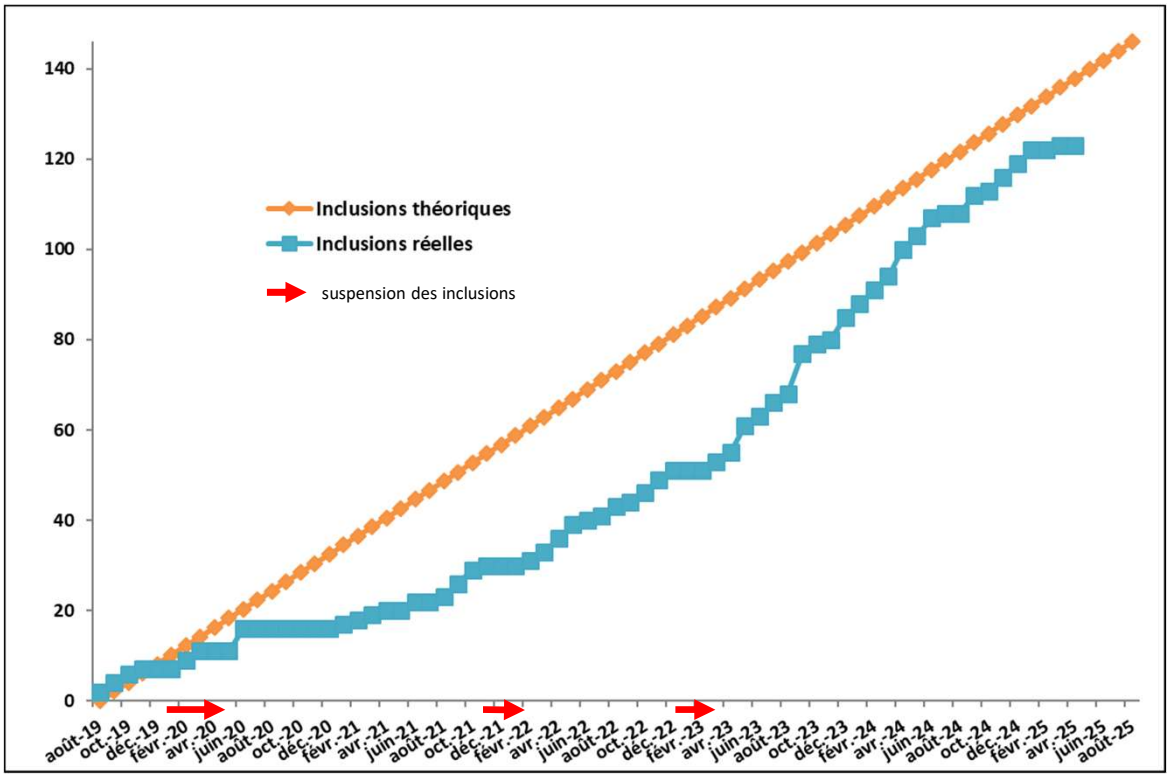
Patients

- 146 patients attendus
- 125 patients inclus
- 109 patient randomisés

Centres

- 52 ouverts, 31 actifs
- Dernières inclusions:
  - APHP Cochin (Pr Puechal)
  - CHRU Lille (Dr Lebas)
  - CH Valenciennes (Dr Quemeneur)
  - CH Amiens (Dr Titeca)

ETAT DES INCLUSIONS



Parution de MAINRITSAN3

Centres actifs	
03-CHU Perpignan	25 - CHU Nantes - Hôtel Dieu
06 - CHU La Cavale Blanche	26 - AP-HP Hôpital Cochin
07 - HCL Louis Pradel	29 - Hôpital Haut Lévêque
08 - CHU Côte de Nacre	30 - HCL CHLS - Service néphrologie
09-CH Niort	34 - Nouvel Hôpital Civil -Médecine interne
11 - CHU Estaing	36 - Nouvel Hôpital Civil – Néphrologie
13 - CHU Dijon - Médecine interne	38 - CH Valenciennes
15 - Centre Hospitalier de Troyes	39-CHU Nancy - Hôpitaux Brabois
16 - Hôpital Claude Huriez CHRU Lille	40 - CH Bretagne Atlantique
17 - CH Agen	43 - Hôpital de Poitiers
18 - HCL HEH - Médecine interne	44 - CHU Nice
20 - HCL Croix Rousse	47 - CHU Amiens – Néphrologie
21 – Hopital La Timone	48 - Boulogne sur Mer
22-Hopital Saint-Joseph-Saint Luc Lyon	51 - CHRU Lille – Néphro
23 - Hôpital de la Conception - Néphrologie	52 - Henri Mondor - Néphro
24 - Hôpital Belle Isle	

Identification lors de l’HDJ M6 post-induction

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On compte sur vous ! Plus que 21 patients !