

MAINRITSEG

MAINTenance of remission with **RIT**uximab versus
azathioprine for patients with newly-diagnosed or relap**S**ing
Eosinophilic **G**ranulomatosis with polyangiitis

A prospective, randomized, controlled, double-blind study.

Xavier PUÉCHAL, Grégory PUGNET, Elisabeth DIOT, Claire DE MOREUIL, Stéphane JOUNEAU, Thomas QUÉMÉNEUR, Gabriel BARRON, Perrine SMETS, Antoine NÉEL, Thomas LE GALLOU, Nicolas NOËL, Yurdagül UZUNHAN, Chloé COMARMOND-ORTOLI, Geoffrey URBANSKI, Ygal BENHAMOU, Alice BÉREZNÉ, Arsène MEKINIAN, Mohamed HAMIDOU, Julien CAMPAGNE, Noémie ABISROR, Benjamin THOREAU, Pascal COHEN, Loïc GUILLEVIN, Philippe RAVAUD, Benjamin TERRIER,
for the French Vasculitis Study Group.

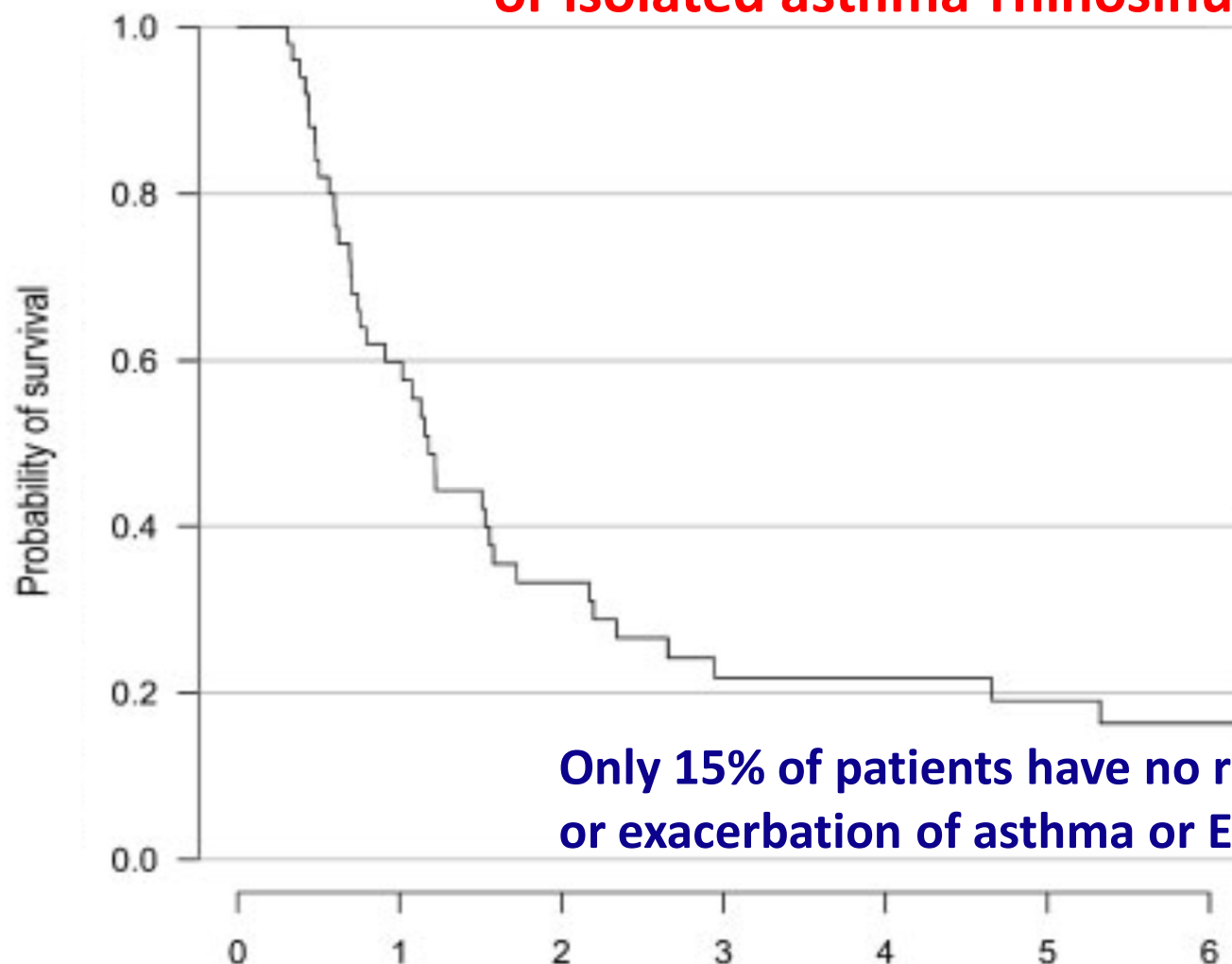


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EGPA Natural history

CHUSPAN 2

**Survival without vasculitis relapse
or isolated asthma-rhinosinus exacerbation**



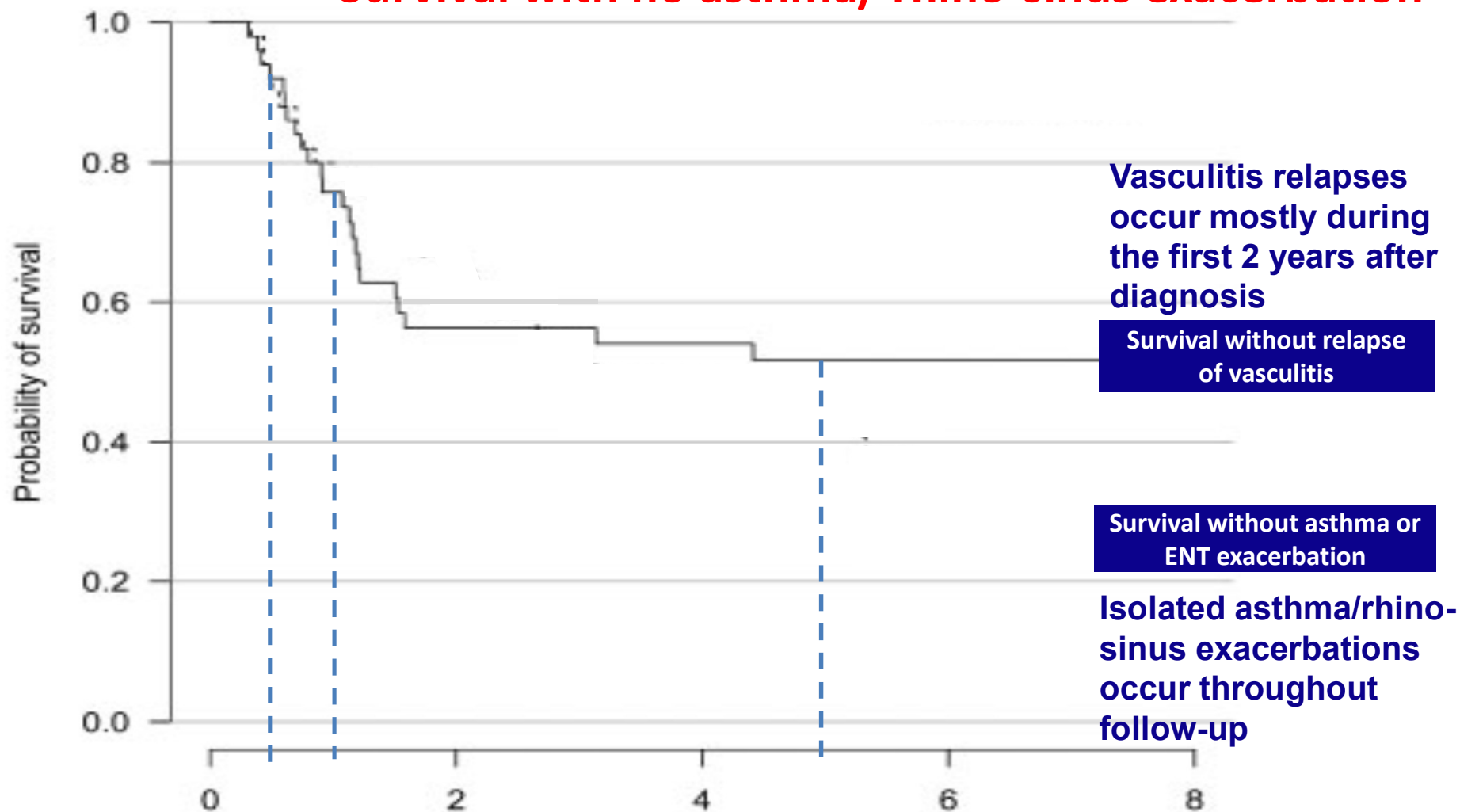
**Only 15% of patients have no recurrence of vasculitis
or exacerbation of asthma or ENT symptoms**

Puéchal X, et al. Rheumatology 2019

CHUSPAN 2

Vasculitis relapse-free survival

Survival with no asthma/ rhino-sinus exacerbation



MAINRITSEG: Objective

Main Objective

To compare RTX with AZA maintenance therapy:

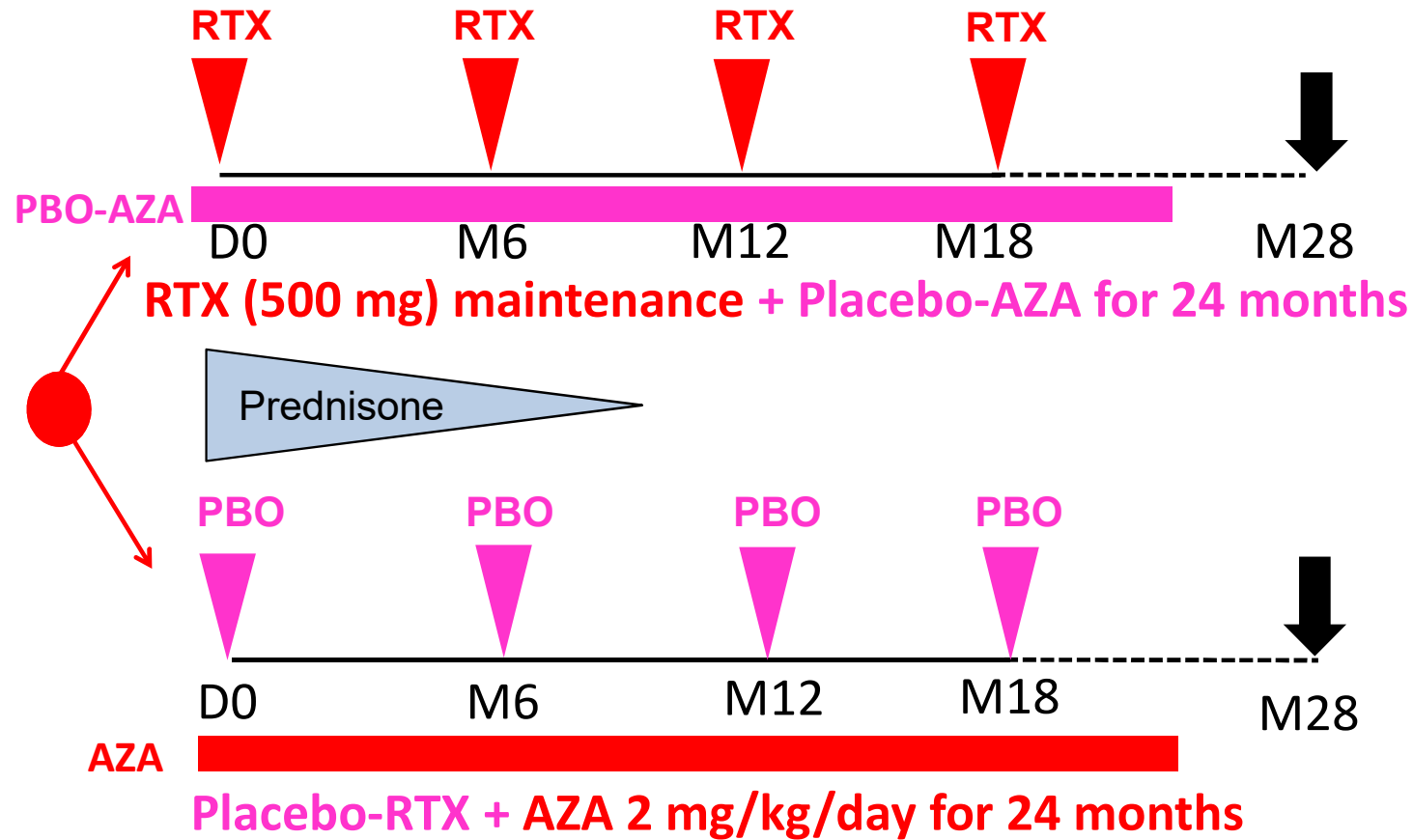
- **on the duration of remission**, defined as the duration in which BVAS=0 and prednisone dose ≤ 7.5 mg/day,
- in patients with EPGA,
- receiving standard of care therapy including GC therapy reduction/withdrawal.

MAINRITSEG: Inclusion criteria

- Patients with a diagnosis of **EGPA**
- **Newly diagnosed or with a vasculitis flare within the past year**
- **vasculitis remission (BVAS=0) following** an induction regimen similar to that used in the REOVAS trial (GC \pm RTX or \pm IV CYC),
- **with a stable GC dose for 30 days or discontinuation of GC,**
- regardless of ANCA status

MAINRITSEG: Design

Primary
endpoint



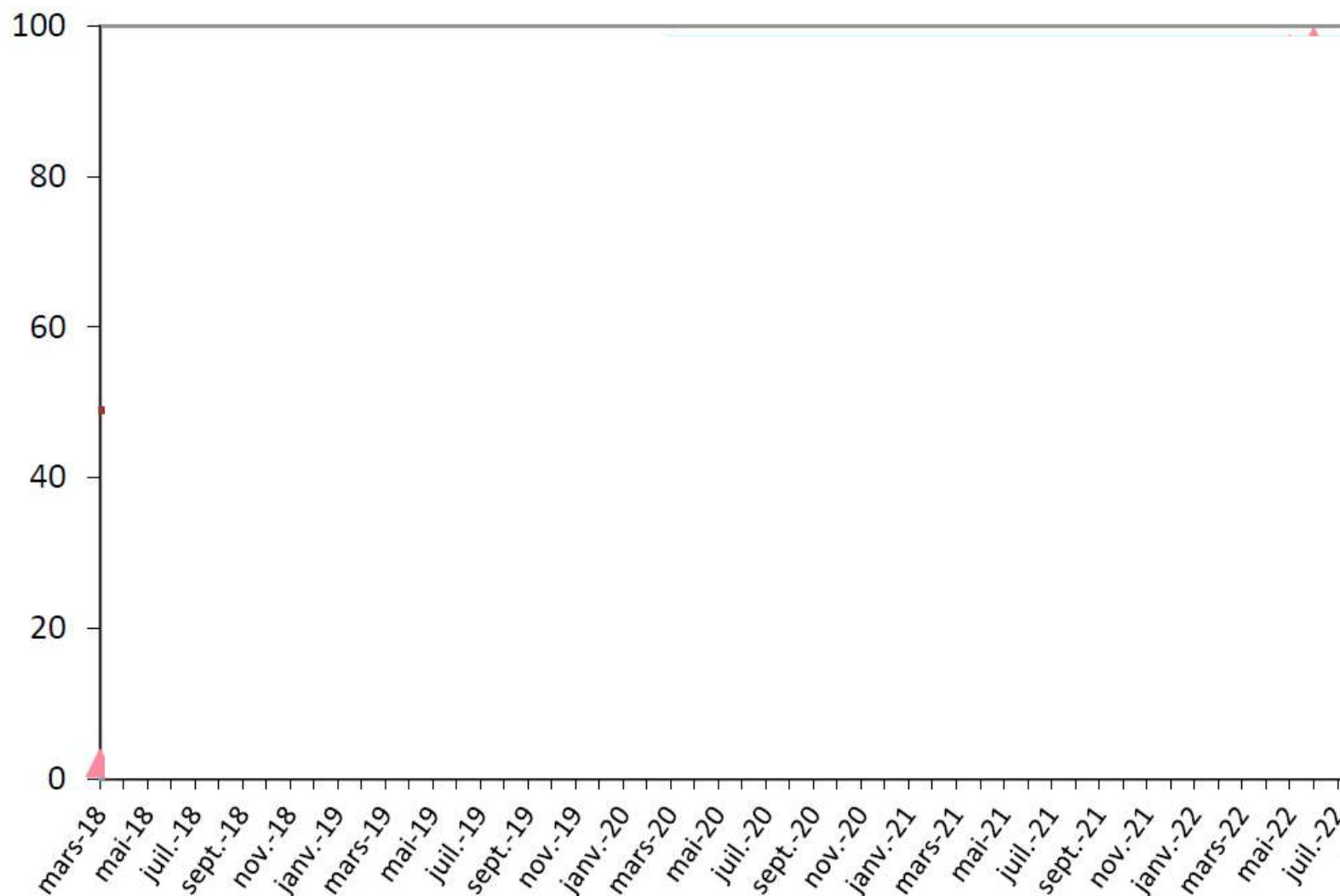
accrued number
of weeks where a
patient remains in
remission with
BVAS=0 and
prednisone ≤ 7.5
mg/day



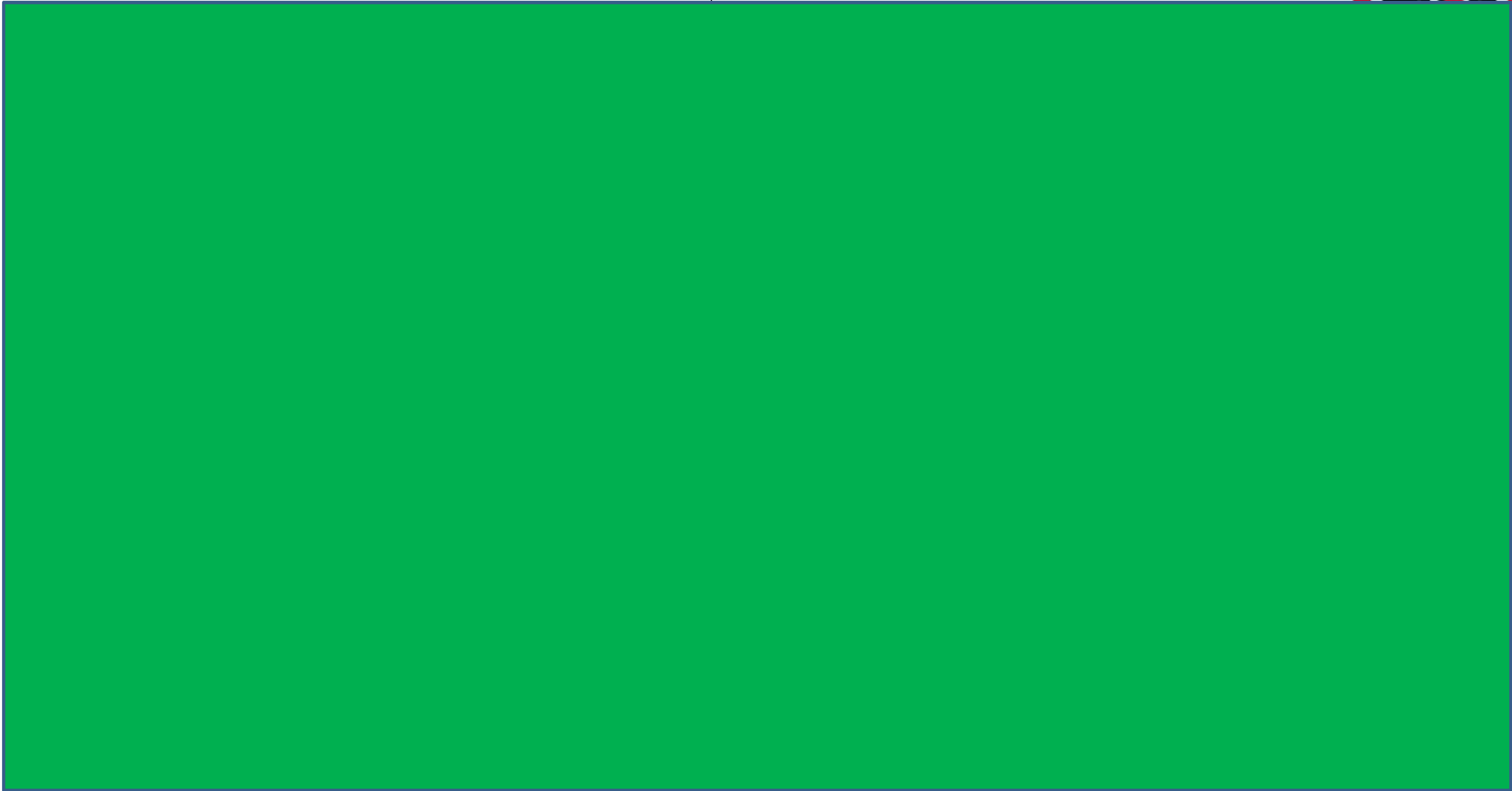
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MAINRITSEG study status

98/98 patients randomized



Randomly assigned (N=98)
in 36 centers



Primary assessment criterion	A (N=49)	B (N=49)	Adjusted mean difference (95% CI)	P

Secondary outcomes	A (N=49)	B (N=49)	% difference (95% CI)	Adjusted relative risk (95% CI)	P

Secondary outcomes, Vasculitis Flares	A (N=49)	B (N=49)
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Kaplan-Meier survival without vasculitis relapse over the 28-month study period



Time since randomization (months)



Secondary outcomes, Asthma/rhinosinusal exacerbations	A (N=49)	B (N=49)
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Clinically significant asthma/rhino-sinusal exacerbation defined as a worsening of disease leading to

- the doubling (or more) of the existing maintenance dose of GCs ≥ 3 days
- or hospital admission or an emergency department visit over the 28 month study period



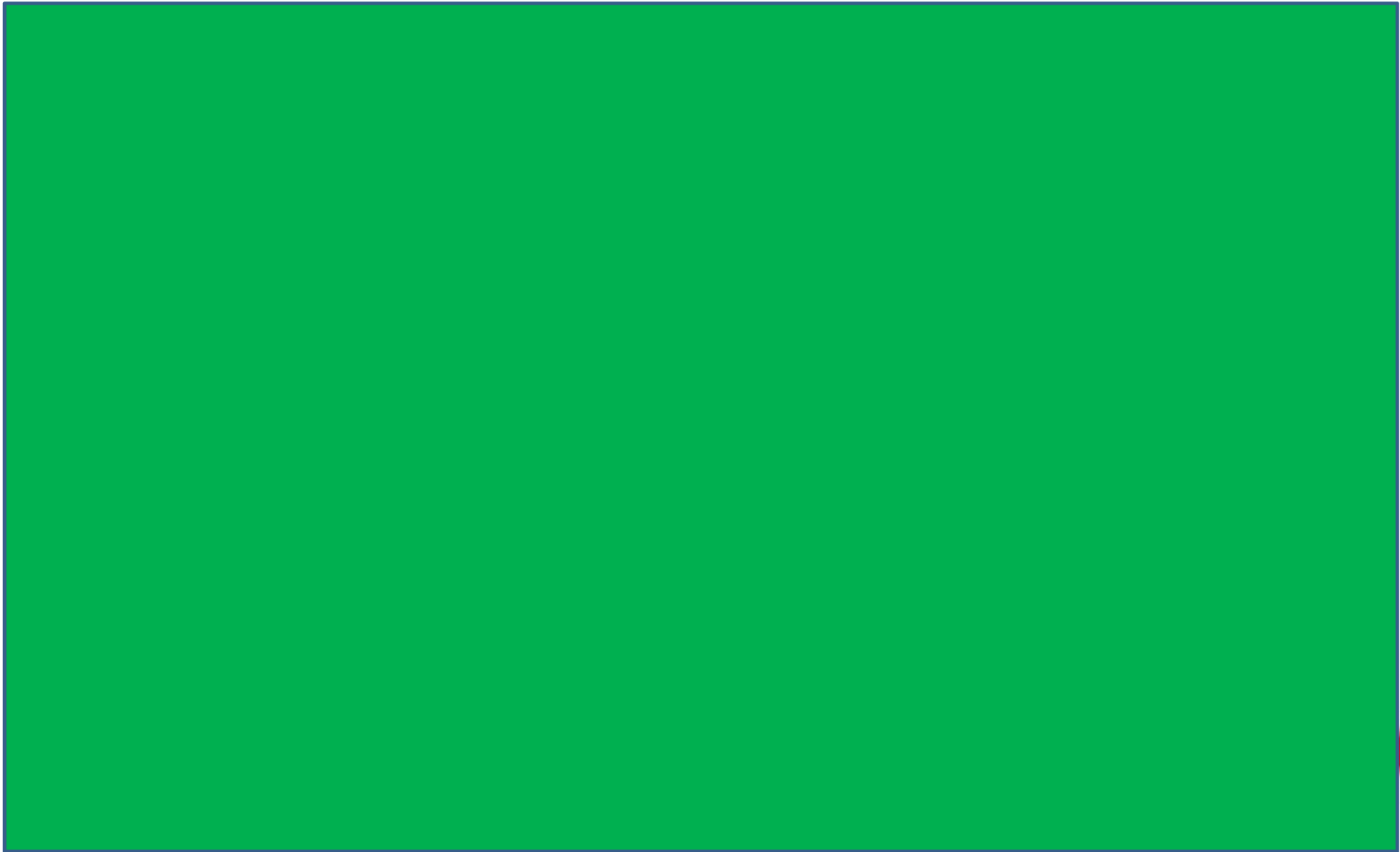
Kaplan-Meier survival without clinically significant asthma/rhinosinusal exacerbations over the 28-month study period



Time since randomization (months)



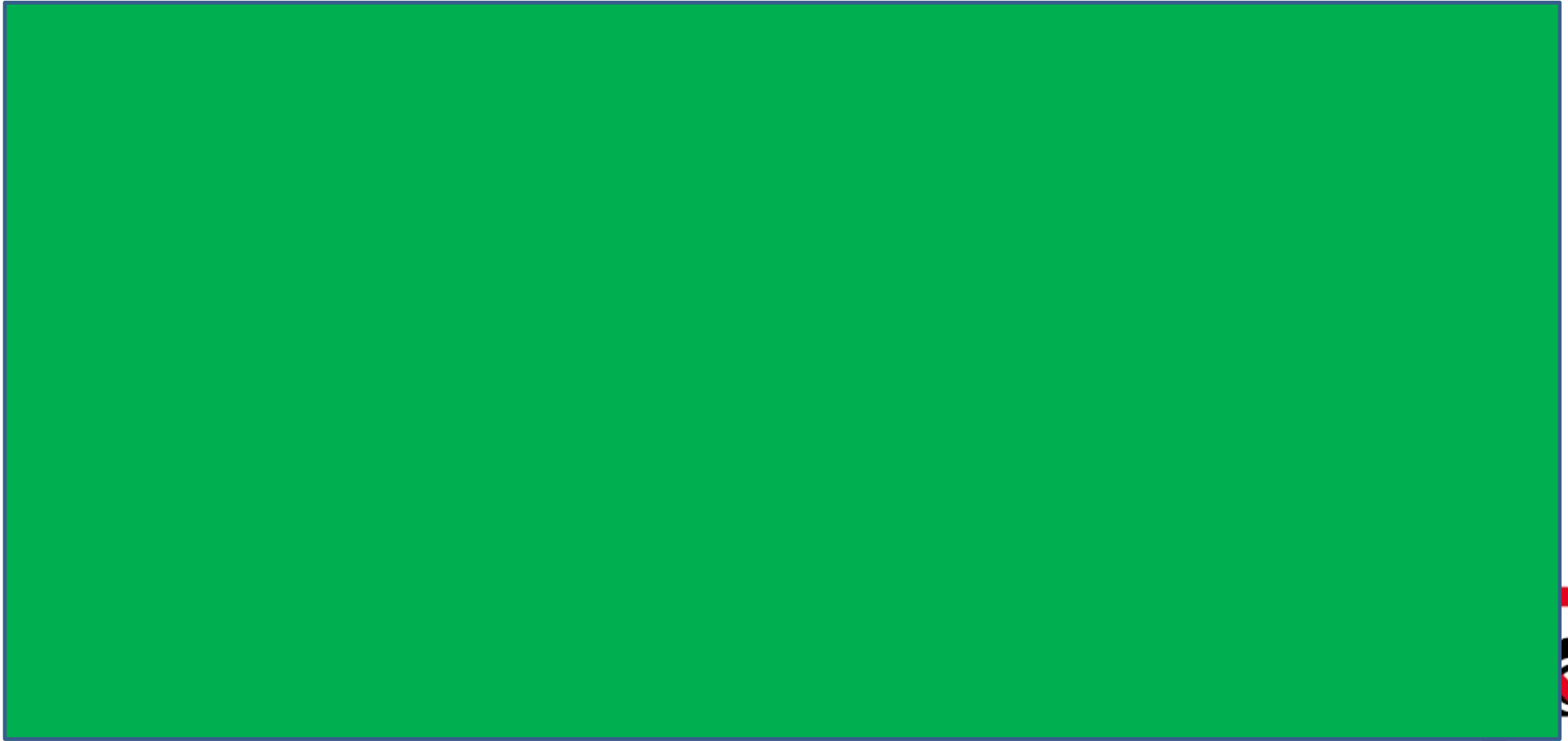
Mean prednisone dose over the 28-month study period





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MAINRITSEG: Preliminary Conclusions



NOVAP

MAINRITSEG: Acknowledgments



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French Vasculitis Study Group investigators: Jonathan LONDON, Paul LEGENDRE, Antoine DOSSIER, Nicolas SCHLEINITZ, Mikael EBBO, Achille AOUBA, Alexandre NGUYEN, Divi CORNEC, Laurent SAILLER, Dominique CHAUVEAU, Pierre DUFFAU, Jean-François VIALARD, Carine GREIB, Cécile DURANT, Sabine REVUZ, François MAURIER, Kim LY, Nicolas LIMAL, Maxime SAMSON, Bernard BONNOTTE, Eric OZIOL, Renaud FELTEN, Nicolas GIRSZYN, Salim TRAD, Julie TRACLET, Mathieu VAUTIER, Antoine FROISSART, Inès AUREAU Julien DESBLACHE, Charles FAISANT, Richard DAMADE, Laure SWIADER, Stanislas FAGUER, Vivien GUILLOTIN, Christian AGARD, Antoine BAUDET, Eric LIOZON, Marc ULRICH, Guillaume ARMENGOL.

Hicham KARDAOUI, Clinical Research Engineer

Marine SAINT BLANCAT, Alexandre MOORES, May LEDRAA, CRA

Elisa MALKI, Adèle BELINO, Alice CAMARA, URC

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Cochin Hospital, Paris, France