

A large-scale trial testing the intensity of CYTOreductive therapy to prevent cardiovascular events In patients with Polycythemia Vera (PV)

ACTRN12609000046202

Status	RECRUITING
Phase	Phase 3
Sponsor	Consorzio Mario Negri Sud
Enrollment	1,000 participants

Plain Language Summary

This study is for people diagnosed with a blood condition called Polycythemia Vera (PV), where the body makes too many red blood cells. Too many red blood cells thicken the blood and raise the risk of stroke and blood clots. The study is comparing two approaches to managing the blood thickness: one that keeps the hematocrit (a measure of red blood cell levels) below 45%, versus one that allows hematocrit to stay between 45% and 50%. Researchers want to find out which target is safer and better at preventing heart and blood vessel problems.

You may be eligible if:

- You are over 18 and up to 85 years old
- You have been diagnosed with Polycythemia Vera (PV) according to WHO criteria
- You are willing and able to follow all study requirements
- You can provide signed informed consent

You may NOT be eligible if:

- You are pregnant, breastfeeding, or a woman of childbearing age without effective contraception
- You are allergic to the study treatments
- You have significant liver or kidney disease
- You have another life-threatening illness (e.g., cancer)
- You have a history of substance or alcohol abuse in the past year

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (4)

- Age > 18 years
- Diagnosis of PV according to World Health Organisation (WHO) criteria
- Ability and willingness to comply with all study requirements
- Written and signed informed consent

Exclusion (6)

- Pregnant or lactating women or women of childbearing potential who are not protected from pregnancy by an accepted method of contraception
- Known hypersensitivity or contraindication to study treatments
- Significant liver (aspartate amino transferasi (AST) or alanine aminotransferasi (ALT) > 2.5 times upper limit normal (ULN)) or renal disease (creatinine > 2 mg/ml)
- Presence of any life-threatening condition or of any disease (e.g. cancer) that is likely to significantly shorten life expectancy

• History of active substance or alcohol abuse within the last year
<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12609000046202>

... and 1 more (see full listing online)

Locations (1 total)

Italy