

# Randomized Controlled Trial in Patients on Long-term Colchicine With Colchicine-resistant Familial Mediterranean Fever (FMF) to Evaluate the Efficacy of On-demand Anakinra Treatment for Painful Attacks in Patients Who Refuse Continuous Daily Therapy

NCT06336733

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Status	RECRUITING
Phase	Phase 3
Sponsor	Assistance Publique - Hôpitaux de Paris
Enrollment	50 participants

## Key Eligibility Criteria

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### Inclusion (13)

- Age  $\geq$  6 years old with no upper limit
  - Proven FMF according to Livneh international criteria and 2 non ambiguous MEFV mutations.
  - Colchicine resistance defined as persistent FMF attack despite the maximum daily posology of colchicine (average one or more attacks per month over a 3-months period)
  - FMF Attack is defined by:
    - Arthritis or
- ... and 8 more (see full listing online)

### Exclusion (19)

- Evidence of active tuberculosis
  - Infection requiring treatment with intravenous antibiotics within 2 weeks prior to inclusion
  - History of recurrent infection (Need more than 4 courses of antibiotic treatment per year (in children) or more  $\geq$  2 times per year (in adults), experience pneumonia twice over any time or  $\geq$  3 bacterial sinusitis in 1 year)
  - Contraindication to anakinra (Hypersensitivity to the active substance or to any of the excipients (Citric acid, anhydrous Sodium chloride, Disodium edetate dehydrate, Polysorbate 80, Sodium hydroxide, Water for injections ) or to E. coli derived proteins
  - Patients with neutropenia (ANC  $<$   $1.5 \times 10^9/l$ )
- ... and 14 more (see full listing online)

## Locations (1 total)

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Service de Médecine interne Hopital Tenon, Paris, France