ARISTEA

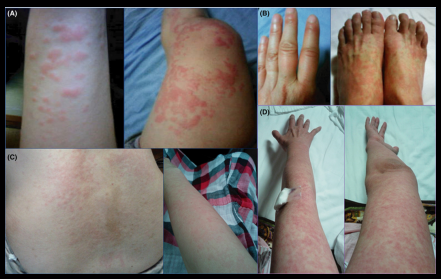
Striding to the forefront of innovative therapeutic options for inflammatory diseases

FAMILIAL MEDITERRANEAN FEVER (FMF)

What is FMF?

Familial Mediterranean fever (FMF) is a rare genetic autoinflammatory disease caused by variants of the *MEFV* gene and it is characterized by recurrent fevers and painful inflammation of the abdomen, chest, and joints

- **FMF is very painful and uncontrolled patients suffer from a poor quality of life**
- **Uncontrolled FMF attacks lead to secondary amyloidosis, which is the primary cause of morbidity and mortality due to cardiac amyloidosis and renal failure**
- **FMF is a rare disease in the United States, with ~19k patients, and it is particularly prevalent in certain Mediterranean populations, including people of Armenian, Turkish, Arabic, and North African Jewish descent, affecting about 1 in 200 individuals in these groups**



What do patients with FMF experience?

Patients with FMF present the following symptoms:

- **Sporadic attacks of fever; 90% of all patients have their first flare before they are 18 years old**
- **Typical cases have a short fever duration of 1 to 3 days and fevers spontaneously resolve**
- **There are individual differences in the frequency of fever flares, and there are various stressors that may precede a fever flare, such as the need for surgery or menstruation**

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What causes FMF?

FMF is a genetic disease caused by a number of mutations in genes affecting a specific protein named pyrin that acts as a major regulatory component of the inflammasome

- Refractory cases occur despite the absence of genetic mutations in the *MEFV* gene
- Because patients with FMF have dysfunctional pyrin, they have a chronic hyper-inflammatory response that is characterized by abundant neutrophilic infiltration into the serosal spaces

What are the available treatments for FMF?

Treatment of FMF aims to prevent acute flares and minimize inflammation between flares in order to prevent progression of amyloidosis

- Colchicine is the first line labeled and approved therapy for FMF and IL-1 antagonists are also approved in most regions
- Notably there are about 30-40% of patients who are not adequately controlled with colchicine alone, which means that these patients continue to have attacks despite maximal tolerable doses of colchicine
- In general, FMF patients who do not respond or who are intolerant to colchicine have very few treatment options

Aristea's Clinical Trial: RIST4721-212

RIST4721-212 is an open-label, single-arm, Phase 2a study to evaluate the safety and efficacy of RIST4721 in subjects with familial Mediterranean fever

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