CompCure ERKReg-Subregistry Prospective Cohort study on C3G and IC-MPGN

STUDY PROCEDURES

ERKNet
The European Rare Kidney Disease Reference Network

compcure

OBJECTIVE

The overall objective of CompCure is to drive better outcome in **C3G and IC-MPGN.**

To do that, an international registry is established to develop a stronger evidence base that will inform clinical decision-making.

CompCure will provide evidence on:

- **The natural history of C3G and IC-MPGN**
- **The diagnostic and prognostic role of completement biomarkers**
- **Better ways to arrive at a correct diagnosis**
- **Personalized, targeted treatment approaches**
- **Getting access / matching patients to new trials**
- **Monitoring of safety and efficacy of new drugs**

The registry is collecting clinical, biochemical and genetic data.

In addition, a **histopathology archive** is established with C3G and IC-MPGN kidney biopsies, as well as a biobank.

PATIENT ENROLMENT

Eligibility Criteria

- Age 0 to 90 yerars
- Newly diagnosed patients with C3G and IC-MPGN
- Patients with a pre-existing diagnosis of C3G and IC-MPGN, for whom well-documented information is available at the time of diagnosis
- Diagnosis confirmed by kidney biopsy
- Excluded: Secondary MPGN

STUDY PROCEDURES

1. **Registry eCRF entries: ERKReg Subregistry, detailed information on immunodiagnostics:**

- At enrolment and annually.
  At treatment change and three months after.

2. **Sampling for Biobank:**

- At enrolment and annually.
  At treatment change and three months after

3. **Submitting histopathology slides:**

- At enrolment and in case of re-biopsy

CompCure welcomes

CompCure welcomes participation from centres who can process, store and send biosamples, and who has a local pathology institute who can digitalize and send histopathology slides.

DOCUMENTS REQUIRED TO GET STARTED:

ERKNet member centres

SUBMISSION of the following documentation to your local ethics committee to obtain EC approval for your center:

- **CompCure study protocol and ethics approval from the Heidelberg Ethics Committee**
- **Patient informed consent form for the CompCure study**
- **CompCure addendum to the ERKReg Data Sharing Agreement (DSA) and Collaboration Agreement (CA)**

External centres (non-ERKNet members)

SUBMISSION of the following documentation to your local ethics committee to obtain EC approval for your center

- **ERKReg and CompCure study protocols with Heidelberg Ethics Committee approval**
- **Patient informed consent forms for both ERKReg and CompCure**
- **ERKReg Data Sharing Agreement (DSA) including the CompCure addendum, and the Collaboration Agreement (CA)**

COMPCURE OFFERS COMPLEMENTARY CENTRALIZED DIAGNOSTIC SERVICES

- Complement/autoimmune panels in reference laboratories in Bergamo, Gdansk, Heidelberg, Nijmegen, Madrid and Paris
- Centralized genetic screening
- Reference pathology
- Possibility of financial support to participating centers for each patient enrolled

HOW TO JOIN THIS PROJECT?

Contact:
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Follow us on compcure.org and LinkedIn, Instagram, Facebook

Find the links www.CompCure.org

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