ForPatients
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Leucemia linfocitica cronica

# Sperimentazione clinica per confrontare venetoclax + obinutuzumab rispetto a fludarabina, ciclofosfamide e rituximab o bendamustina e rituximab in soggetti con leucemia linfatica cronica

A Study to Compare the Efficacy and Safety of a Combined Regimen of Venetoclax and Obinutuzumab Versus Fludarabine, Cyclophosphamide, and Rituximab (FCR)/ Bendamustine And Rituximab (BR) in FIT Patients With Previously Untreated Chronic Lymphocytic Leukemia (CLL) Without DEL (17P) or TP53 Mutation

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Attiva, non in fase di reclutamento | 5 Countries | NCT04285567 2019-003327-37 2023-504036-17-00 CO41685 |

*Le informazioni sono reperite direttamente dai siti web di registri pubblici come ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com ecc. e non sono state modificate.*

## *Official Title:*

Studio di fase III, prospettico, in aperto, multicentrico, randomizzato, volto a confrontare l'efficacia e la sicurezza di un regime di associazione di venetoclax e obinutuzumab rispetto a fludarabina, ciclofosfamide e rituximab (FCR)/bendamustina e rituximab (BR) in pazienti idonei (FIT) affetti da leucemia linfatica cronica (LLC) non trattata in precedenza senza mutazione DEL(17P) o TP53

## *Trial Summary:*

Questo studio valuterà l'efficacia e la sicurezza di venetoclax e obinutuzumab (VEN + G) rispetto a fludarabina + ciclofosfamide + rituximab o bendamustina + rituximab (FCR/BR) in partecipanti idonei (FIT) (per FIT si intende un punteggio nella Cumulative Illness Rating Scale # 6 e una clearance della creatinina nella norma # 70 mL/min) affetti da LLC non trattata in precedenza senza mutazione DEL(17P) o TP53 con necessità di trattamento. I partecipanti ammissibili saranno assegnati in modo casuale in rapporto 1:1 al trattamento con VEN + G (Braccio A) o FCR/BR (Braccio B).

| Hoffmann-La Roche | Fase III |
|---|---|
| Sponsor | Phase |

**NCT04285567 2019-003327-37 2023-504036-17-00 CO41685**
Trial Identifiers

## *Eligibility Criteria:*

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| Gender | Age | Healthy Volunteers |
| --- | --- | --- |
| **All** | **#18 Years** | **No** |

**How does the CRISTALLO clinical trial work?**
This clinical trial is recruiting people who have a type of disease called chronic lymphocytic leukemia (CLL). In order to take part in this trial, patients must have CLL that they have not previously been treated for.

The purpose of this clinical trial is to compare the effects, good or bad, of different treatments for patients with CLL. In this clinical trial, you will get either venetoclax plus obinutuzumab, or fludarabine and cyclophosphamide plus rituximab, or bendamustine plus rituximab.

**How do I take part in this clinical trial?**
To be able to take part in this clinical trial, you must have CLL.

You must not have received previous treatment for CLL and you cannot join the trial if you are pregnant.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

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**What treatment will I be given if I join this clinical trial?**
Everyone who joins this clinical trial will be split into 2 groups randomly (like flipping a coin) and given either:

- GROUP A: venetoclax, given as a tablet to swallow, plus obinutuzumab given as an infusion (a slow injection) into the vein
    - Patients in this group will receive 12 rounds of treatment; each round lasts for 28 days
    - Obinutuzumab is given every week for the first 3 weeks of Round 1, then once a month for Rounds 2–6
    - After the first 3 weeks of Round 1, venetoclax is given every day up until the end of the trial
- OR GROUP B: the clinical trial doctor will decide whether you receive fludarabine, cyclophosphamide and rituximab OR bendamustine and rituximab given as infusions (through a drip) into the vein
    - Patients in this group will receive 6 rounds of treatment; each round lasts for 28 days. Clinical trial doctors will decide which of the two treatments available in this group is best for you:
    - Treatment 1: patients will receive rituximab on the first day of each round and fludarabine and cyclophosphamide infusions will be given on the first 3 days of each round
    - Treatment 2: patients will receive rituximab on the first day of each round and bendamustine on the first 2 days of each round

You will have an equal chance of being placed in either Group A or Group B.

**How often will I be seen in follow-up appointments and for how long?** You will be given the clinical trial treatments venetoclax plus obinutuzumab for 12 months or fludarabine, cyclophosphamide and rituximab/bendamustine and rituximab for 6 months. You are free to stop this treatment at any time. After receiving treatment, you will be seen regularly by the clinical trial doctor. These visits will include checks to see how you are responding to the treatment and any side effects that you may be having.

**What happens if I am unable to take part in this clinical trial?** If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

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For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT04285567

Trial-identifier: NCT04285567

## *Inclusion Criteria:*

Per ulteriori informazioni riguardanti lo studio e i criteri di inclusione, clicca sul seguente codice: NCT04285567

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