About Research Studies

Pharmaceutical companies use research studies like the Ri-CoDIFy study to learn more about investigational drugs. The information collected in research studies helps determine whether an investigational drug could one day be made available to the public.

Research studies are voluntary, which means you do not have to participate. Even if you do agree to participate, you are free to leave the study at any time and for any reason. Your decision whether to participate in or leave a research study will in no way affect your medical care.

If you choose to participate in the Ri-CoDIFy study, you will help to advance science. You will contribute to progressing the field of research in CDI treatments by allowing researchers to gain a better understanding of the role of ridinilazole, a novel targeted antibiotic, in the treatment of CDI and the prevention of recurrence.

For more information, please contact:

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Ri-CoDIFy 1 Ri-CoDIFy 2

[1]Davies, K.A., et al. (2014). "Underdiagnosis of *Clostridium difficile* across Europe: the European, multicenter, prospective, biannual, point-prevalence study of *Clostridium difficile* infection in hospitalized patients with diarrhea (EUCLID)." Lancet Infect Dis **14**(12): 1208-1219.

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IRB Approved at the
Protocol Level
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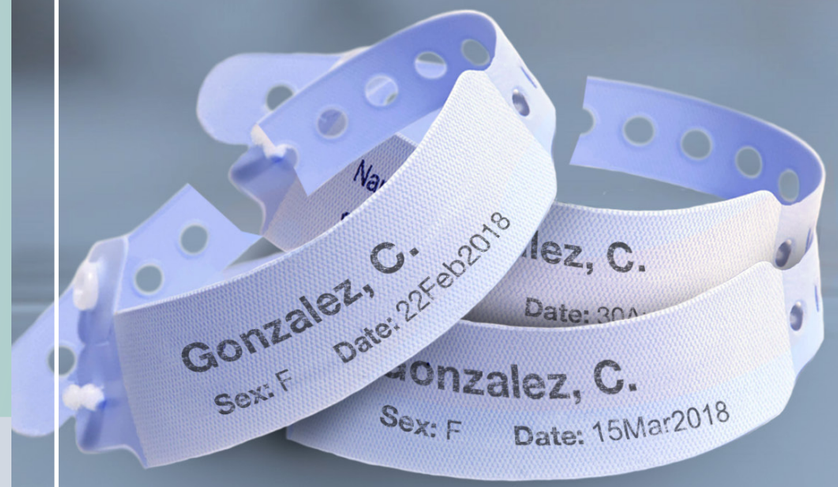
How do we prevent recurrences of *C. diff* infections?

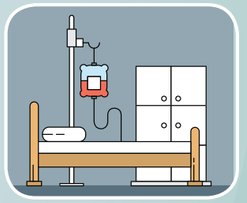


Recurrence of *Clostridium difficile* infection (CDI) is an unmet medical need in CDI management. Learn about this research study of an investigational drug for CDI treatment.

What is *Clostridium difficile* infection (CDI)?

CDI is an infection of the gut that usually occurs after antibiotic use. Although anyone can develop CDI, it mostly affects people who are over the age of 65 and in the hospital. Symptoms can include diarrhea, stomach pain, and fever.

CDI is difficult to treat and can return in people who have had it before. In fact, up to 30% of patients who first get CDI may experience a second infection. For patients who experience a second recurrence of CDI, as many as 65% will have another episode of CDI. The European Union estimates for hospital CDI are 6.6 cases per 10,000 patient bed days, with about 23% of cases being undiagnosed, suggesting that the actual incidence may be much higher[1].



Recurrent episodes of CDI often occur because of the continued or repeated use of antibiotics, which results in a disruption of the healthy balance of microorganisms in the gut. *Clostridium difficile* bacteria are kept in check by the healthy balance of the complex groups of microorganisms in the gut. Disruption of this balance leads to an overgrowth of C. difficile bacteria with a consequent recurrence of CDI.

What is the purpose of the **Ri-CoDIFy** study?

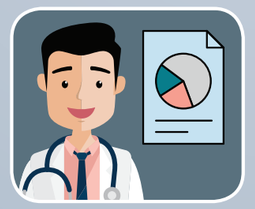
Doctors in this study want to learn more about an investigational drug called ridinilazole when it is given to patients with CDI. Ridinilazole is a novel antibiotic that is highly selective at targeting and killing C. difficile. Because it is highly selective, ridinilazole causes less damage to the healthy balance of microorganisms in your gut when compared to other antibiotics prescribed for treatment of CDI. Researchers think this could help reduce the chance of recurrence of CDI.

In this study, doctors want to assess how safe and effective ridinilazole is at both curing CDI and reducing the risk of CDI returning over a three-month period.

Ridinilazole will be compared to vancomycin, which is an approved antibiotic often used to treat CDI. Ridinilazole, previously administered to 56 healthy subjects and 69 patients with CDI, has been noted to be safe and well tolerated. In patients with CDI, ridinilazole was effective in both curing the initial CDI and reducing the rate of subsequent recurrence of CDI.

However, since these results were seen in a small study of 69 patients with confirmed CDI, a much larger study involving many more patients is necessary to confirm that ridinilazole is safe and effective in achieving a sustained clinical response affording a cure of the initial infection without any recurrence.

The results of this study will help doctors learn more about ridinilazole and whether it could one day be approved as a treatment for CDI.



Who can be in the **Ri-CoDIFy** study?

To pre-qualify for this study, you must:

- Be 18 years of age or older
- Have diarrhea (3 or more unformed bowel movements a day)

You should not participate in this study if you have:

- Recently had more than one prior episode of CDI in the previous 3 months or more than 3 episodes in the past 12 months
- Inflammatory Bowel Disorder (Crohn's disease or ulcerative colitis)
- Already had more than 24 hours of dosing of antimicrobial treatment active against CDI for the current episode of CDI

All study-related visits, tests, and drugs will be provided at no cost. In addition, reimbursement for study-related travel may be provided.

What will happen during the **Ri-CoDIFy** study?

If you are eligible and you agree to participate, you will be randomly assigned (like flipping a coin) to receive either ridinilazole or vancomycin. You and your study doctor will not know which study drug (ridinilazole or vancomycin) you are receiving. However, in the event of an emergency, this information can be provided.

You will take your assigned study drug 4 times per day for 10 days. You will be asked to complete an electronic diary every day to document your bowel movements. You will be asked to return to the study clinic up to 6 times to have your health evaluated through various tests and assessments. You may also receive phone calls from the study staff. Your total study participation will last about 3 months.