The relationship between efficacy, medical problems and CD22 level measured by a local laboratory in people with acute lymphoblastic leukemia who received inotuzumab ozogamicin

Date of summary: December 2019
Study number: NCT01564784 | **Study start date:** August 2012 | **Study end date:** January 2017

The full title of this abstract is: Efficacy and Safety Outcomes in the Phase 3 INO-VATE Trial by Baseline CD22 Positivity Assessed by Local Laboratories

Inotuzumab ozogamicin is approved to treat the condition under study that is discussed in this summary.

Researchers must look at the results of many types of studies to understand whether a study drug works, how it works, and whether it is safe to prescribe to patients.

This summary reports the results of only one study. The results of this study might be different from the results of other studies that the researchers look at.

More information can be found in the scientific abstract of this study, which you can access here:
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Click to find out how to say tricky medical terms

- **Acute lymphoblastic leukemia** <uh-KYOOT LIM-foh-BLAS-tik loo-KEE-mee-uh>
- **ALL** <A-ell-ell>
- **Inotuzumab ozogamicin** <in-noh-TOO-zoo-mab OH-zoh-ga-MIH-sin>
- **Lymphoblast** <LIM-foh-BLAST>

What did this study look at?

- Acute lymphoblastic leukemia (ALL for short) is a type of blood cancer. In ALL, the body makes too many of a type of white blood cell called a lymphoblast.
  - In some people, the cancer can become undetectable but then comes back (known as a relapsed ALL), or the cancer can stop responding to treatment (known as refractory ALL).
- Inotuzumab ozogamicin (InO for short) is a treatment for people with refractory or relapsed ALL (R/R ALL for short).
  - ALL cancer cells can have a protein called CD22 on their surface.
  - InO works by finding and destroying ALL cancer cells with CD22.
- Researchers demonstrated the efficacy* of InO in reducing ALL cancer cells in people with R/R ALL. On average, these people lived longer than the people who had chemotherapy.
  - The researchers saw this effect in people with high levels of CD22 as well as people with low levels of CD22.
  - A central laboratory measured levels of CD22 for all people.
- Outside clinical studies, CD22 levels are usually measured in local laboratories, which are close to where people receive treatment.
  - For this part of the study, the researchers wanted to know whether the level of CD22 measured in local laboratories affected:
    - the efficacy of the treatment with InO or standard chemotherapy, and
    - what kind of medical problems** people experienced after treatment with InO or standard chemotherapy.
- This summary describes:
  - how people with different levels of CD22 responded to InO or chemotherapy, and
  - what kind of medical problems people with different levels of CD22 who received InO experienced.

* Efficacy is how well a drug works within a clinical trial.
** Medical problems could be caused by reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could have been caused by a study treatment, or by another medicine the participant was taking.

Who took part in this study?

164 people with R/R ALL received InO

162 people with R/R ALL received chemotherapy

The researchers divided people into 4 groups based on their level of CD22:

- Group 1: low level of CD22
- Group 2: low to medium level of CD22
- Group 3: medium to high level of CD22
- Group 4: high level of CD22

What were the results of the study?

- Local laboratories were able to measure CD22 in 152 people who received InO and 152 people who received chemotherapy.
- In all 4 groups, the average level of CD22 was similar in people who received InO compared with people who received chemotherapy.
- People who received InO were more likely to have a complete response than people who received chemotherapy. This was the case for all levels of CD22.
  - This was also the case when the researchers used very sensitive methods to detect cancer cells.
    - A complete response means that no cancer cells were detected in the blood or bone marrow after people received a treatment for their cancer.

How many people had a complete response?

	Group 1: low CD22	Group 2: low to medium CD22	Group 3: medium to high CD22	Group 4: high CD22
InO	82%	68%	73%	77%
Chemotherapy	41%	37%	27%	21%

On average, how long did people live after they started treatment?

	Group 1: low CD22	Group 2: low to medium CD22	Group 3: medium to high CD22	Group 4: high CD22	Groups 2, 3 and 4 taken together
InO	9 months	6 months	8 months	9 months	7 months
Chemotherapy	12 months	8 months	5 months	6 months	6 months

On average, how long did people live without their cancer getting worse?

	Group 1: low CD22	Group 2: low to medium CD22	Group 3: medium to high CD22	Group 4: high CD22	Groups 2, 3 and 4 taken together
InO	6 months	3 months	6 months	5 months	5 months
Chemotherapy	2 months	2 months	2 months	1 month	2 months

In people who had a complete response, how long did this response last on average?

	Group 1: low CD22	Group 2: low to medium CD22	Group 3: medium to high CD22	Group 4: high CD22	Groups 2, 3 and 4 taken together
InO	6 months	4 months	5 months	5 months	5 months
Chemotherapy	7 months	4 months	3 months	3 months	3 months

- People with higher levels of CD22 (Groups 2, 3 and 4) who received InO were more likely to:
  - live longer after starting treatment
  - live longer without their cancer getting worse, and
  - maintain a complete response.
- It is important to keep in mind that the number of people in each group was small, making it more difficult to reach definite conclusions.
- Low numbers of certain blood cells (a condition called cytopenia) was the most common severe medical problem*** in people who received InO. Rates of cytopenia were similar for all levels of CD22 (between 31 and 53 in 100 people).

*** A medical problem is considered "severe" when it limits daily activities such as bathing and dressing, is disabling or is medically significant, or could be life-threatening, need hospital care, or cause lasting problems.

Other severe medical problems:

	Group 1: low CD22	Group 2: low to medium CD22	Group 3: medium to high CD22	Group 4: high CD22
Infections	21%	26%	37%	31%
Increased levels of a liver protein in the blood	5%	8%	2%	11%
Blocked blood vessels in the liver	13%	8%	7%	17%

More results from this study can be found here:
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What were the main conclusions reported by the researchers?

- In this study, treatment of R/R ALL with InO was more effective than chemotherapy, regardless of the level of CD22 measured by local laboratories.
- Although the number of people treated was low, people with higher CD22 levels were more likely to:
  - live longer after starting treatment
  - live longer without their cancer getting worse, and
  - maintain a complete response.

Who sponsored this study?

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The sponsors would like to thank all of the people who took part in this study.

Further information

Click to show more information on the study and clinical trials in general

For more information on this study, please visit:
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