

The weight loss effects and safety of trial drug BYM338 for people who are overweight and have type 2 diabetes



Thank you!

Thank you to the participants who took part in the clinical trial for the drug **BYM338**. All of the participants helped the researchers learn more about how BYM338 works and how safe it is to take.

Novartis sponsored this trial and believes it is important to share what was learned from the results of this trial with the participants and the public. An independent organization prepared this summary of the trial results.

We hope this helps the participants understand their important role in medical research.

Trial information

Trial number: CBYM338X2211

Drug studied: BYM338

Sponsor: Novartis

You can find **more information** about this trial by going to the websites listed on **page 11** of this summary.



If you participated in the trial and have **questions** about the results, please speak with the trial doctors or staff at your trial site.

This trial at a glance

What was the purpose of this trial?

[Read more on page 3](#)



This trial was designed to learn more about the trial drug BYM338. BYM338 is designed to help the body build muscle and lose body fat. This trial focused on how well BYM338 worked for people who are overweight or obese and have type 2 diabetes.

This trial was designed to answer these questions:

- Did the participants who received BYM338 lose more body fat than the participants who received the placebo after 48 weeks?
- What medical problems did the participants have in this trial?
Keeping track of the medical problems helped to learn about the safety of BYM338.

Who was in this trial?

[Read more on page 3](#)



- 78 men and women were in this trial
- The participants were 42 to 76 years old, were overweight or obese, and had type 2 diabetes

What treatments did the participants receive?

[Read more on page 4](#)



The participants were assigned to receive one of these treatments:

- BYM338
- Placebo – looks like the trial drug, but has no trial drug in it. Using a placebo helps researchers better understand the actual effects of a trial drug.

The participants received their assigned treatment every 4 weeks through a needle in a vein, which is called an intravenous infusion, or an IV infusion.

What were the main results of this trial?

[Read more on page 6](#)



Participants who received BYM338 lost more body fat than participants who received the placebo.

Most of the participants had at least one medical problem. The most common medical problem was diarrhea. The clinical trial team concluded that BYM338 was safe for the participants in this trial.

[This trial had other results along with the main results.](#)

[Read more on page 10](#)

What was the purpose of this clinical trial?

Researchers are looking for better ways to treat people who are overweight or obese and have type 2 diabetes. **Obesity** is when someone is overweight for their height from too much body fat. Obesity raises a person's chance of having other serious health problems, including type 2 diabetes.

Type 2 diabetes is a disease in which the body doesn't use blood sugar the way it should. It causes high blood sugar levels, which can lead to serious health problems over time, such as kidney damage, nerve damage, and heart disease. Many people who have obesity also have type 2 diabetes.

BYM338, also called bimagrumab, is a trial drug designed to help the body build muscle and lose body fat. Past trials have shown that this drug may also help the body control blood sugar levels.

BYM338 is not yet approved for use. Before a drug can be approved for people to take, researchers do many trials to find out how safe it is and how it works.

This trial was designed to answer these questions:

- Did the participants who received BYM338 lose more body fat than the participants who received the placebo after 48 weeks?
- What medical problems did the participants have in this trial?
Keeping track of the medical problems helped to learn about the safety of BYM338.

Who was in this trial?

78 people began this trial, and 3 participants left the trial before treatment. 75 of the participants received a trial treatment – 40 men and 35 women. All participants were 42 to 76 years old. Their average age was 60.

At the start of this trial, each participant:

- Had a body mass index, also called **BMI**, that showed they were overweight or obese
- Had been diagnosed with type 2 diabetes and had an A1C between 6.5-10%
- Could continue to take certain diabetes treatments during the trial
- Was otherwise in good overall health

What is BMI?

BMI is a measure based on someone's weight and height. A high BMI can mean someone is overweight or obese.

This trial took place in the United Kingdom and the United States.



For more information about who could and could not be in this trial, and the participants in this trial, visit novctrd.com. Use trial number **CBYM338X2211** to find the scientific summary.

What treatments did participants receive?



A computer program was used to randomly assign each participant to receive one of these treatments:

- **BYM338:** 10 milligrams (mg) for each kilogram (kg) of their body weight. The highest amount of BYM338 a participant could receive was 1,200 mg.
- **Placebo:** A placebo looks like the trial drug but has no trial drug in it. Using a placebo helps researchers better understand the actual effects of a trial drug.

Using a computer program to assign the treatments helped make sure the results were compared as fairly as possible.



All participants received their treatment through a needle in a vein, which is called an intravenous infusion, or an IV infusion, that lasted about 30 minutes.

Participants and trial staff did not know what treatment each participant received during the trial. Some trials are done this way because knowing what treatment participants receive can influence the results. Not knowing what treatment participants receive helps make sure the results are looked at fairly.

What happened during this trial?

The trial began in February 2017 and ended in May 2019. 20 participants did not complete this trial:

- 3 participants left the trial before receiving any trial treatment
- 17 left after receiving at least one trial treatment

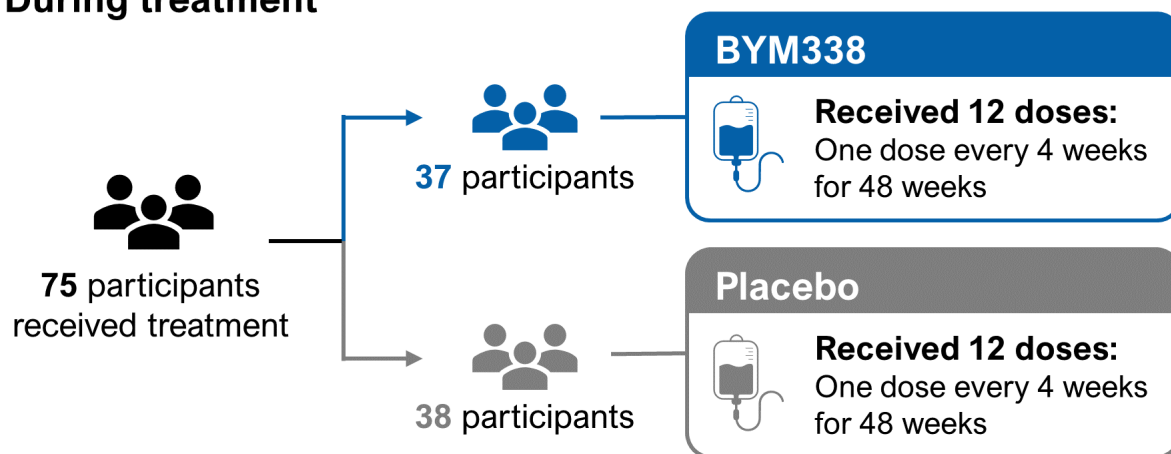
Trial staff measured participants' body fat during visits to the trial site before, during, and after treatment. To do this, the staff used a type of scan called DXA or dual energy X-ray absorptiometry. A **DXA** scan is a type of x-ray that measures each part of the body, including fat and muscle.

How this trial was done:

Before treatment

- The trial doctors checked each participant's health, BMI, and type 2 diabetes to make sure they could be in this trial
- The trial staff measured each participant's body fat with a DXA scan
- About 3 weeks before treatment, the trial doctors asked the participants to follow an exercise and nutrition program
- 78 participants joined this trial and 3 participants left before treatment

During treatment



During visits to the trial site, the trial staff measured a participant's:

- Body fat and muscle with a DXA scan
- Height, weight, and other body measures
- Blood sugar levels and how well their body responded to insulin

The trial doctors asked the participants to continue to:

- Follow an exercise program to increase physical activity
- Eat a nutritious, low-calorie meal plan
- Take certain diabetes treatments, if needed

After treatment

- 4 and 8 weeks after treatment, each participant returned to the trial site for the trial doctors to check their health

What were the main results of this trial?



This is a summary of the overall results of this trial. Individual results from each participant may be different and are not included in this summary.

Researchers need many trials to learn if a drug or other treatment is safe and works well. Other trials may provide new information or different results. Always talk to a doctor before making any changes to your health care.

Did the participants who received BYM338 lose more body fat than the participants who received the placebo?



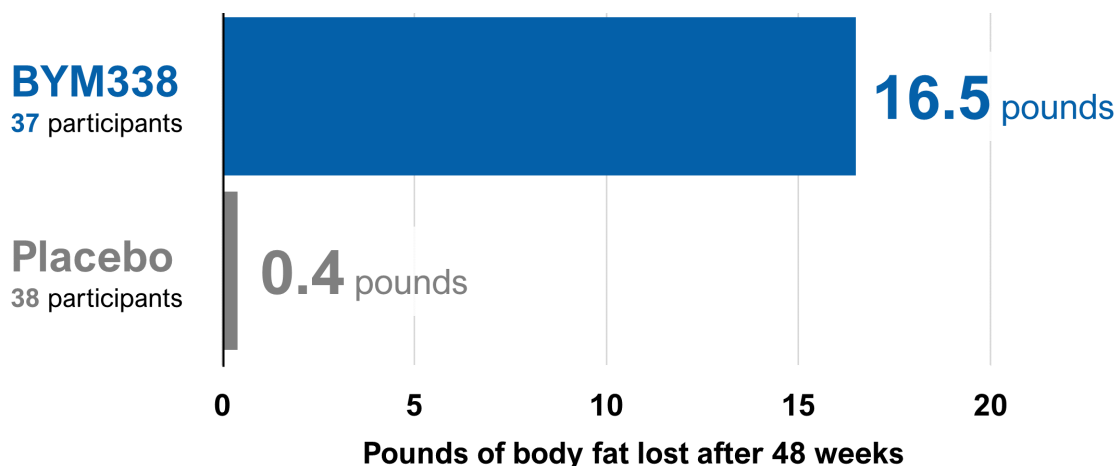
The participants who received BYM338 lost more body fat than the participants who received the placebo.

To find this out, the clinical trial team looked at the DXA scans that measured each participant's body fat before, during, and after treatment. The team then compared the average change in body fat for the participants who received BYM338 to the participants who received the placebo.

After 24 weeks of treatment, the participants who received BYM338 had lost body fat. Those who received the placebo had about the same amount of body fat as when they started treatment.

At the end of the 48 weeks of treatment, the participants who received BYM338 had lost more body fat. Those who received the placebo still had about the same amount of body fat as when they started treatment. The chart below shows the average amount of body fat participants lost after 48 weeks of treatment.

The average amount of body fat the participants lost after 48 weeks



What medical problems did participants have in this trial?

Medical problems that happen during trials are called “adverse events”. An **adverse event** is any unwanted sign or symptom that participants have during a trial. An adverse event is considered “**serious**” when it is life-threatening, causes lasting problems, the participant needs hospital care, or results in death.









Adverse events may or may not be caused by treatments in the trial. Many trials are needed to know if a drug or treatment causes an adverse event. Trial doctors keep track of all adverse events that happen in trials, even if they do not think the adverse events might be related to the trial treatments.



The clinical trial team concluded BYM338 was safe for the participants in this trial.

Trial doctors looked for adverse events when they checked participants’ health at the trial site. Participants also reported adverse events.

Participants who had adverse events

Participants who had:	BYM338 Out of 37 participants	Placebo Out of 38 participants
Serious adverse events	8%  3 of 37	8%  3 of 38
Other adverse events	84%  31 of 37	82%  31 of 38
Left this trial due to adverse events	14%  5 of 37	0%  0 of 38

What serious adverse events happened?

BYM338

About 8%, or 3 of the 37 participants, who received BYM338 had a total of 4 serious adverse events. These were:

- **Lung infection**
(pneumonia)
- **Pain below the ribs**
(abdominal pain upper)
- **Pancreas inflammation**
(pancreatitis)
- **Possible sign of pancreas injury**
(lipase increased)

Placebo

About 8%, or 3 of the 38 participants, who received the placebo had a total of 5 serious adverse events. These were:

- **Blocked blood flow to the heart**
(acute coronary syndrome)
- **Sudden heart attack**
(acute myocardial infarction)
- **Heat burn** (thermal burn)
- **The stomach doesn't empty food as it should**
(impaired gastric emptying)
- **Skin infection** (cellulitis)

During this trial, no other participants reported serious adverse events, including deaths.











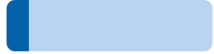

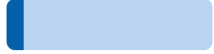

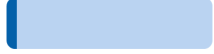

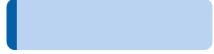

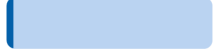

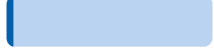
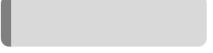
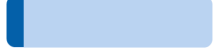
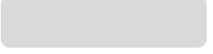
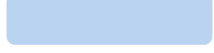

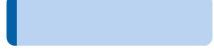

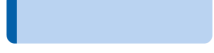

What other adverse events happened?

Some participants reported adverse events that were not serious. The table on the next page reports adverse events that 3 or more participants had during this trial. Other adverse events were reported by fewer participants.



For more information about all the adverse events reported by participants in this trial, visit novctrd.com. Use trial number **CBYM338X2211** to find the scientific summary.

Types of adverse events that were not serious

Participants who had:	BYM338 out of 37 participants	Placebo out of 38 participants
Diarrhea	41%  15 of 37	11%  4 of 38
Muscle spasms	41%  15 of 37	3%  1 of 38
Upper respiratory tract infection Such as a common cold or the flu	16%  6 of 37	13%  5 of 38
Possible sign of pancreas injury Lipase increased	11%  4 of 37	5%  2 of 38
Headache	0%  0 of 37	13%  5 of 38
Feeling sick to the stomach Nausea	11%  4 of 37	0%  0 of 38
High blood pressure Hypertension	8%  3 of 37	3%  1 of 38
Rash	5%  2 of 37	5%  2 of 38
Decreased appetite	5%  2 of 37	3%  1 of 38
High blood sugar Hyperglycaemia	3%  1 of 37	5%  2 of 38
Joint pain Arthralgia	3%  1 of 37	5%  2 of 38
Low red blood cell levels Anemia	8%  3 of 37	0%  0 of 38
Muscle pain Myalgia	0%  0 of 37	8%  3 of 38
Pain in the belly area Abdominal pain	5%  2 of 37	3%  1 of 38
Throwing up Vomiting	5%  2 of 37	3%  1 of 38

What other results were learned?

At trial visits before, during, and after treatment, trial staff measured the participants' blood sugar levels, body measurements, and how well the body responded to insulin. The clinical trial team learned that, compared to the participants who received the placebo, the participants who received BYM338:

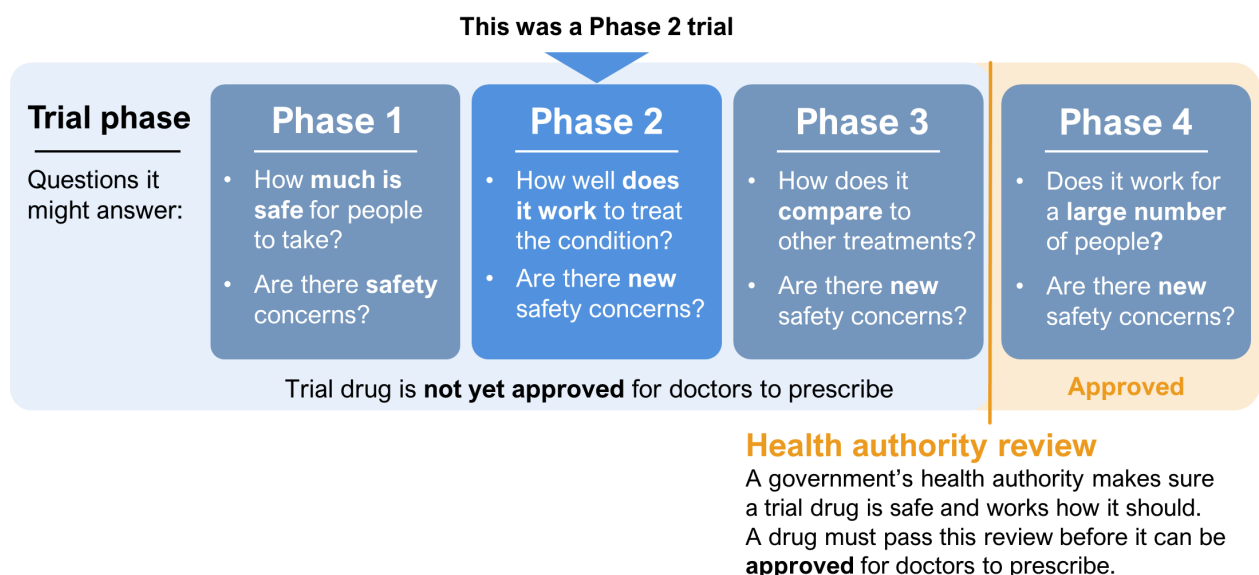
- Had lower blood sugar levels on average
- Lost more weight and lowered their BMI and waist size. They also had gained more lean body mass, such as muscle.

The team concluded that more trials are needed to know if BYM338 affects how well the body responds to insulin, which is also called insulin resistance.

What was learned from this trial?

This was the first trial to learn about how well BYM338 works for people who are overweight or obese and have type 2 diabetes. The clinical trial team found that BYM338 was safe for participants in this trial, and that participants who received it lost more body fat than those who received the placebo.

This was a Phase 2 trial, which learns about the safety of a trial drug and how well it works in a small number of participants. This was one of many trials a drug must go through before it can be approved for people to use. The chart below shows these phases and what questions they're designed to answer.





The results presented here are for one trial. One trial cannot give a complete picture of the benefits and risks of a trial drug. The results of many trials are needed to find out which treatments can be used for people who are overweight or obese and have type 2 diabetes. This summary shows only the main results from this trial. Other trials may provide new information or different results.

Where can I learn more about this and future clinical trials?



This is a summary of the results for one trial.

You can find detailed results and more information about this clinical trial on the Novartis Clinical Trial Results website:

1. Visit novctrd.com
2. Click on “Clinical trial results and trial summary for patients” at the top right of the page
3. Read and scroll down, then click “I accept” to agree to use the information and the website
4. Select “Search by study number” on the bottom left of the page
5. Type “**CBYM338X2211**” in the search box and click search

If you would like to view the website in a language other than English, you can click the “Google Translate” button on the top right of the page.



If you were in this trial and have questions about the results, please speak with the doctor or staff at your trial site.

This trial was registered on the following websites:

- ClinicalTrials.gov – <https://clinicaltrials.gov/>
To find this trial, type **CBYM338X2211** in the **Other terms** search box
- European Union Clinical Trials Register –
<https://www.clinicaltrialsregister.eu/ctr-search>
To find this trial, type **CBYM338X2211** in the search box

Full trial title:

A randomized, subject- and investigator-blinded, placebo-controlled study to assess the safety, pharmacokinetics and efficacy of intravenous bimagrumab in overweight and obese patients with type 2 diabetes

If more trials are planned, they will appear on the public websites listed on the next page or at www.novartisclinicaltrials.com. When there, search for **BYM338**.

Thank you!

Novartis would like to thank all of the people who participated in this clinical trial. The participants made this clinical trial possible and helped researchers answer important health questions and learn about a possible medical treatment. Many volunteers and many clinical trials are needed to advance medical science.



Novartis is a global healthcare company based in Switzerland that provides solutions to address the evolving needs of patients worldwide.

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