Study of a new version of exenatide, a treatment for people with diabetes that is given using a mini-pump under the skin

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What did this study look at?

- This study looked at ITCA 650, a new version of the medication exenatide (also called Byetta or Bydureon). This treatment helps to control the blood sugar levels of people with diabetes.
- This treatment is usually given by injection. Some people find it difficult to take medications by injection. So they may not stay on the treatment long-term.

Exenatide is pronounced <ex-EN-a-tide>

It is also called Byetta <bye-YET-a> or Bydureon <bye-JAW-e-on>

- The new version is given through a mini-pump. This is placed under the skin and releases the medication over 3–6 months. It is still under development.
- The researchers found that the new version of the medication effectively controlled the blood sugar of people with diabetes.

Who could take part in the study?

This study was done in

OVER 100 HOSPITALS

in the United States

460

460 people with type 2 diabetes took part in the study

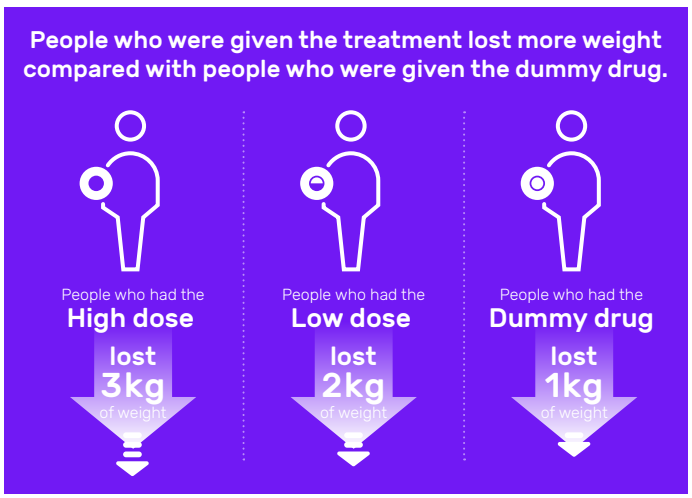
- Both men and women took part
- Their average age was about 55 years

These people usually managed their diabetes using diet, exercise and tablets, but their blood sugar levels were still too high

- **One-third had a high dose of the treatment**
- **One-third had a low dose of the treatment**
- **One-third had a dummy drug (placebo)**

What were the results of the study?

- **After 9 months, people who were given treatment had improved long-term blood sugar control compared with people who were given the dummy drug.**
  - Long-term blood sugar control was similar in people who had the high dose and people who had the low dose.
- **People who were given the treatment had more side effects than people who were given the dummy drug.**
  - The most common side effect was feeling sick (nausea).
    - Nausea was seen in about 3 out of 10 people who received the treatment.
    - Nausea was usually seen at the start of treatment and got better during the first few weeks of treatment.
- **Side effects were similar between people who had the high dose and people who had the low dose.**



How could this study benefit patients?

- People who are not able to have injections can receive the same treatment using a mini-pump.
- This could help them to keep taking the treatment and manage their diabetes better.
- One study is not enough to find out if a new medicine works. Other studies may find different results than those in this summary.

How to use this summary to help patients and doctors talk about this research

- **Question from patient to doctor:** How important is this research to my care?
- **Question from doctor to patient:** How relevant is this research to what matters most to you?

Are there any plans for future studies?

- This study is completed.
- Other studies of this medicine are completed.
- No other studies are planned yet.

Who sponsored this study?

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Intarcia Therapeutics would like to thank all of the people who took part in this study.

Further information

Study number: NCT01455857 | **Study start date:** March 2013 | **Study end date:** September 2014

To find out more information on this study, please visit:
- https://clinicaltrials.gov/ct2/show/NCT01455857

To find out more information on clinical studies in general, please visit:
- https://www.clinicaltrials.gov/ct2/about-studies/learn
- http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are

The full title of this article is:
Efficacy and safety of ITCA 650, a novel drug-device GLP-1 receptor agonist, in type 2 diabetes uncontrolled with oral antidiabetes drugs: The FREEDOM-1 study

You can find the full article here:
https://www.ncbi.nlm.nih.gov/pubmed/29242349
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