Chronic myeloid leukemia (CML for short) is a type of cancer that affects white blood cells. It tends to progress slowly over many years.

- CML is caused by the formation of a gene called BCR-ABL, which causes the cancer cells to increase in number.
- Genes are segments of DNA* and are found in structures called chromosomes within each cell of the body. The BCR-ABL gene is found in a chromosome called the Philadelphia chromosome, which is present in some types of leukemia cancer cells but not in normal blood cells.
- BCR-ABL creates an abnormal tyrosine kinase that is more active than normal.

Bosutinib is a type of medicine known as a tyrosine kinase inhibitor (TKI for short).

- Tyrosine kinases are proteins in the body that control how cells grow and divide.
- Bosutinib works by blocking specific tyrosine kinases in the cancer cells, causing them to die.
- Bosutinib is approved to treat people who have:
  - newly diagnosed CML
  - CML that is no longer responding to treatment with other TKIs (such as imatinib, dasatinib, and nilotinib)
  - stopped their previous treatment because they could not tolerate it.

Not much is known about the effects of bosutinib during pregnancy.

In this summary, the researchers looked at information from Pfizer’s safety database, which had information about people who conceived a baby while taking bosutinib.

- Any pregnancies found on the database up until February 28, 2018 were included.

This analysis describes what happened when:

- Women taking bosutinib became pregnant, or
- Women, whose male partners were taking bosutinib, became pregnant.

* DNA (scientific name, deoxyribonucleic acid) contains genetic information that regulates activity inside a cell.
Who was included in this patient group analysis?

- The researchers found 33 reports of pregnancies that happened when women, or their male partners, were taking bosutinib.
  - 16 women taking bosutinib became pregnant.
  - 17 men taking bosutinib had a partner who became pregnant.
- The researchers looked at what happened at the end of the pregnancy.
  - 24 pregnancies had known outcomes.
  - 9 pregnancies had unknown outcomes.

What were the results of this patient group analysis?

**Women taking bosutinib who became pregnant**

- Of the 16 women taking bosutinib who became pregnant:
  - Most stopped taking bosutinib upon pregnancy
  - 6 gave birth to a live baby
  - 3 had an abortion: 2 by choice and 1 due to medical reasons
  - 1 had a miscarriage, which was not related to bosutinib
  - 6 outcomes were unknown.
- In 5 of the 6 live births, the mothers had stopped taking bosutinib, 2 at 5 weeks of pregnancy, and 3 at an unknown time.
  - The babies were healthy at birth and were born via vaginal delivery.
- 4 of the 6 live births reached full term.
  - Information was not available for the other 2 live births.

**Men taking bosutinib whose partner became pregnant**

- Of the 17 men taking bosutinib whose partner became pregnant:
  - 9 women gave birth to a live baby
  - 4 women had an abortion: 3 by choice and 1 for medical reasons
  - 1 woman had a miscarriage, which was not related to bosutinib
  - 3 outcomes were unknown.
- Of the live births, all 9 babies were healthy at birth.
  - 1 baby was delivered by Caesarean section.
  - 8 of the 9 live births reached full term.

What were the main conclusions reported by the researchers?

- It is recommended that bosutinib should not be taken at any time during pregnancy.
  - It is recommended to discuss the possible risks of taking bosutinib during pregnancy, when applicable.
  - Women should stop taking bosutinib if they become pregnant.
  - It is recommended that women of childbearing potential have a pregnancy test before starting bosutinib treatment.
  - People taking bosutinib should use effective contraception.
- Nearly one-half of the pregnancies resulted in healthy newborns. Most women stopped taking bosutinib upon pregnancy.
- The next most common outcome was abortion. Most of these were abortions by choice or for medical reasons. None of these cases were considered to be related to bosutinib.
- No abnormalities considered to be caused by bosutinib were seen in babies born to women taking bosutinib, whose male partners were taking bosutinib.
- The results of this analysis are similar to pregnancy reports in people taking other TKIs.

Who sponsored this analysis?

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Pfizer would like to thank all of the people who took part in this analysis.

Further information

For more information on this analysis, please visit:

[View Scientific Article](https://www.futuremedicine.com/doi/10.2217/ijh-2020-0004)

For more information on clinical studies in general, please visit:

[https://www.clinicaltrials.gov/ct2/about-studies/learn](https://www.clinicaltrials.gov/ct2/about-studies/learn)

[http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are](http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are)

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