

**Paper Reference(s) 4BI1/2B**  
**Pearson Edexcel International GCSE (9–1)**

**Biology**  
**Unit: 4BI1**  
**PAPER: 2B**

**Source Booklet for Question 1**

**DO NOT RETURN THIS  
SOURCE BOOKLET WITH THE  
QUESTION PAPER.**

Read the passage below. Use the information in the passage and your own knowledge to answer Question 1 in the Question Paper.

## Male contraception

Hormonal contraception has been used by women for many years to control their fertility. A recent study investigated a new contraceptive injection to be used by men.

The study was done in seven different countries: the United Kingdom, Australia, Germany, Italy, India, Indonesia and Chile. The researchers investigated a total of 320 healthy men aged between 18 and 45, all with female partners aged between 18 and 38. 5

All the men had normal sperm counts and produced sperm with no abnormalities in shape or movement. They had no sexually transmitted infections and no medical or mental health illnesses. Their female partners were healthy and did not intend to become pregnant within the next two years. They were willing to accept a low, but unknown, chance of becoming pregnant. 10 15

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The study had two phases. These were the initial suppression phase lasting 26 weeks, followed by a contraceptive effectiveness testing phase lasting just over one year. In the suppression phase, the men were given injections of a drug called progestin and the hormone testosterone. This was repeated at 8, 16 and 24 weeks. Progestin inhibits sperm production and reduces the release of testosterone. Semen samples were collected every two weeks to monitor the sperm count. During this phase, couples had to use alternative barrier methods of contraception, such as condoms.

When a man had produced two consecutive semen samples with a sperm count of less than one million per  $\text{cm}^3$ , they began the contraceptive effectiveness testing phase. During this phase, the men continued to receive regular injections every eight weeks for just over one year. Semen samples were taken at the same time as each injection to monitor the sperm count. If the sperm count went above one million per  $\text{cm}^3$ , the injections were stopped. At this point the men left the trial and other methods of contraception were resumed.

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The contraceptive injections prevented pregnancies in the partners of 98·4% of the men. However, a number of men reported side effects. For example, just under half of the men developed acne (skin infections and irritation) and one in five reported mood disorders. 45

In approximately 5% of the men, their sperm count had not returned to normal one year after stopping the injections. Despite the side effects, more than three-quarters of the men, and their partners, said they would be happy to continue to use this new method of contraception. 50

The scientists concluded that this was a valuable early-stage trial that gave a good indication of the potential safety and effectiveness of the progestin and testosterone injections for male contraception. 55

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