

## Data from clinical trials

### Introduction

This activity has a similar format to many of the AS Science in Society exam questions. It presents data from clinical trials and tests understanding of many of the ideas in this topic.

### Suggested mark scheme

See next page for suggested mark scheme.

#### How Science Works

- Ad** A set of repeat measurements can be summarised by stating an average value (mean) and an indication of the spread of values. Useful visual representations are error bars on graph points.
- Ae** To judge if there has really been a change in the value of a quantity, we need to take account of both the difference in the mean values and the spread of repeat measurements. It is hard to detect a small change in the mean value of a quantity when the range of values in the data set is greater than the change being detected.
- Af** In many situations, scientists have to observe or measure a sample of the objects or cases they are studying (for example, observations in the field, cases of an illness, etc.). Data are more reliable if systematic sampling and observing/measuring methods are used.
- Fd** In assessing how much trust to place in a reported scientific claim, it is important to assess the extent to which it has been subjected to peer review.
- Hc** Society exercises controls on the development and application of science and technology. Official regulations apply to many kinds of scientific activity. Regulatory bodies are set up to implement these controls.

a	i	<ul style="list-style-type: none"> <li>Two groups treatment and control</li> <li>Control group given dummy/inactive drug</li> </ul>	1 mark each	2
	ii	selected participants are assigned to the two groups at random	1 mark	1
	iii	<ul style="list-style-type: none"> <li>obesity</li> <li>no other serious health problems</li> <li>informed consent</li> </ul>	any 2 for 1 mark each	2
b	i	<ul style="list-style-type: none"> <li>greater weight loss than control group</li> <li>loss of 7 kg not enough</li> <li>only 4 –5 kg lost compared with control group</li> <li>after 18mo weight may be rising again</li> </ul>	any 2 for 1 mark each	2
	ii	<ul style="list-style-type: none"> <li>has some benefit /3 – 4kg lost</li> <li>appears that it is hard to maintain loss/ weight rising again</li> </ul>	any 1 for 1 mark	1
c		peer reviewed /explanation of peer review	for 1 mark	1
d	i	<ul style="list-style-type: none"> <li>The control group also lost weight, because of the diet and the placebo effect</li> <li>The difference between the two groups shows how much of the weight loss in the Orlistat group is due specifically to the drug</li> </ul>	any 2 for 1 mark each	2
	ii	<ul style="list-style-type: none"> <li>95% confidence that the true result is within that range</li> <li>it indicates the range/ spread of results</li> </ul>	any 1 for 1 mark each	1
	iii	<ul style="list-style-type: none"> <li>all trials showed some benefit / results have been repeated</li> <li>more uncertainty about amount of weight loss</li> </ul>	any 2 for 1 mark each	2
e		<ul style="list-style-type: none"> <li>obesity increases the risk of serious diseases /heart disease/diabetes</li> <li>these cost the NHS much more than the cost of the anti-obesity drugs</li> <li>cost benefit analysis shows that the drugs could save the NHS money</li> </ul>	any 2 for 1 mark each	2
f	i	<ul style="list-style-type: none"> <li>do not give a licence until trials give full information available</li> <li>carefully balance risks and benefits</li> <li>do not give a licence if risks too severe</li> <li>make sure information on risks is available to prescribers and patients</li> <li>continue monitoring even after licence granted</li> </ul>	any 3 for 1 mark each	3
	ii	<ul style="list-style-type: none"> <li>do not prescribe to those who may already be at risk of these side effects</li> <li>monitor anyone receiving the drug very carefully</li> </ul>	any 1 for 1 mark	1
g		this question is marked according to the level descriptors below		6
				26*

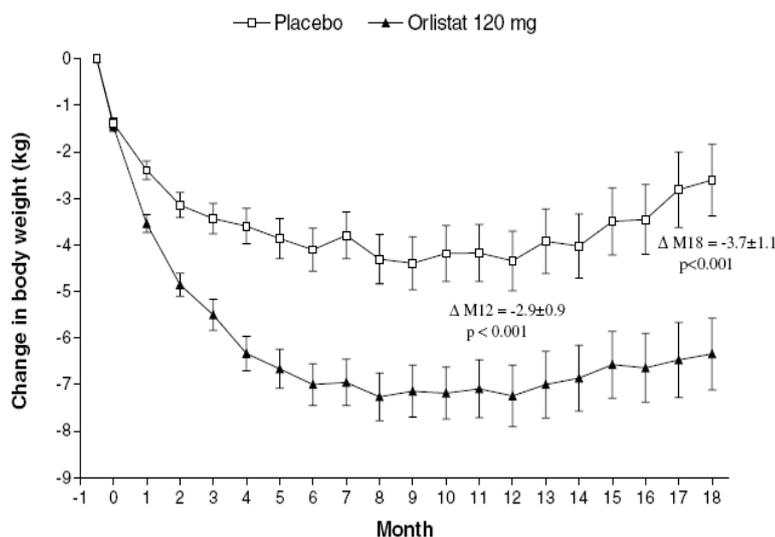
**\*this question is considerably longer than a real exam question would be**

Level	Descriptor	Mark range
	An answer will meet most of the criteria given in the level descriptor	
3	Good Claims supported by an appropriate range of evidence Good use of information or ideas about science going beyond those given in the question Argument well structured with minimal repetition or irrelevant points Accurate and clear expression of ideas with only minor errors of grammar, punctuation and spelling	5 - 6
2	Modest Claims partially supported by evidence Good use of information or ideas about science given in the question but limited beyond this The argument shows some attempt at structure The ideas are expressed with reasonable clarity but with a few errors of grammar, punctuation and spelling	3 - 4
1	Limited Valid points but not clearly linked to an argument structure Limited use of new information or ideas about science Unstructured Errors in grammar, punctuation and spelling or lack of fluency	1 - 2
0	Incorrect or no response	0

## Data from clinical trials

Many people have difficulty restricting their diet leading to obesity. Obesity can increase the risk of serious diseases such as heart disease and diabetes. It has been suggested that for some people drugs may be an effective way of helping them lose weight. Clinical trials have studied the effectiveness of such drugs. **Figure 1** shows the results of one such trial.

**Figure 1** Change in body weight over time with *Orlistat, 120mg plus diet* versus *placebo plus diet*



<http://www.nature.com/ijo/journal/v27/n5/pdf/0802281a.pdf>

(a) The trial was a double-blind randomised placebo controlled trial.

(i) Explain the meaning of *placebo controlled trial*.

(2 marks)

(ii) What does it mean to say the trial is *randomised* in this context?

(1 mark)

(iii) How do you think the participants would have been selected for this trial?

(2 marks)

(b) Both groups were being given support to control their diet but only one group was given Orlistat.

- (i) Do the results of this trial suggest that Orlistat is an effective drug for reducing body weight? Explain your answer.

(2 marks)

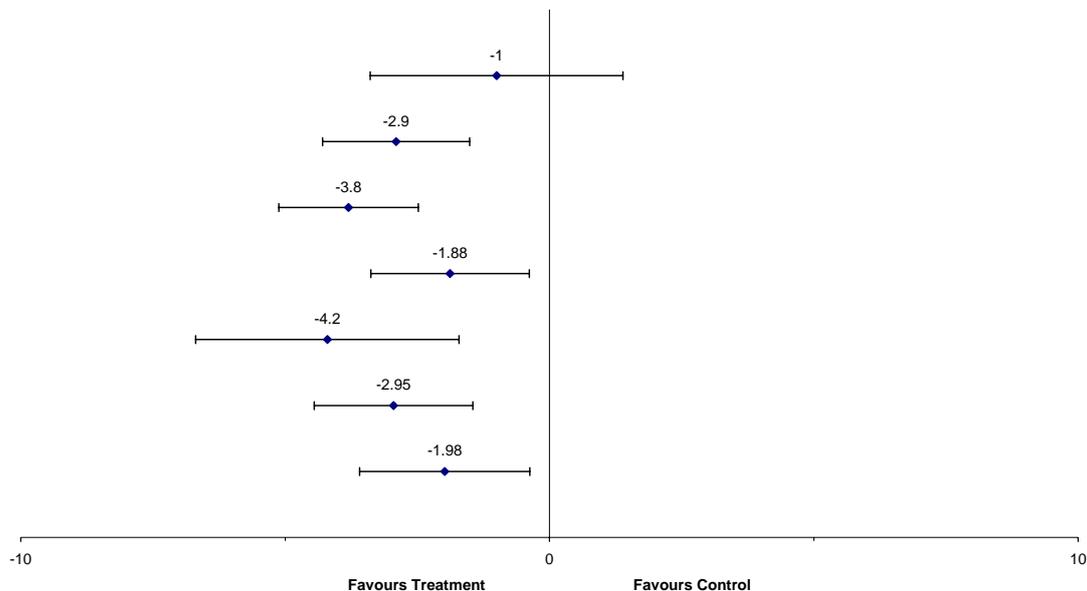
- (ii) Do the results indicate that dieting is an effective way of reducing body weight? Explain your answer.

(1 mark)

(c) This research was published in a respected academic journal, the International Journal of Obesity. Explain why this gives us confidence in the reliability of the results and conclusions.

(1 mark)

Figure 2 Mean weight lost with placebo minus weight lost with Orlistat for different studies



(d) **Figure 2** compares the results of several similar trials.

- (i) Why is the difference in weight loss between the two groups, rather than simply the weight loss on Orlistat, chosen as the measure of effectiveness?

(2 marks)

- (ii) Each point represents the mean weight difference for the study. What information is given by the horizontal lines through each point?

(1 mark)

- (iii) Does the information in **Figure 2** increase or decrease your confidence in the effectiveness of Orlistat? Explain your answer.

(2 marks)

(e) Annual treatment with drugs such as Orlistat costs about £1000 per patient per year. Suggest why the National Institute for Clinical Excellence, NICE, has decided that this is good value for money for the NHS.

(2 marks)

(f) There are risks associated with using drugs to reduce weight. Some very effective drugs also increase blood pressure, others increase the risk of psychiatric disorders.

(i) How can the Medicines and Healthcare Products Regulatory Agency, MHRA, take measures to minimise the risks of such adverse effects?

(3 marks)

(ii) How can those prescribing the drugs act to minimise these risks?

(1 mark)

- (h) Although these anti-obesity drugs are licensed for prescription only it is possible to buy them on the internet after completing an online consultation. Do you think this is a good idea? Discuss the advantages and disadvantages of internet availability of such drugs.

The marks awarded for this question include an assessment of the quality of your written communication.

(6 marks)

**Total 26**