

Medical Statistics

Exercises 2

(Released 14 November 2011 work submitted by ~Tuesday 29 November 2011 will be marked and returned. Work submitted after solutions are made available will not be marked)

- 1) Given below is an edited extract from an SPSS session analysing the results of a two period crossover trial to investigate the effects of two treatments A (standard) and B (new) for cirrhosis of the liver. The figures represent the maximal rate of urea synthesis over a short period and high values are desirable. Patients were randomly allocated to two groups: the 8 subjects in group 1 received treatment A in period 1 and B in period 2. Group 2 (13 subjects) received the treatments in the opposite order.
 - i) Specify a suitable model for these data which incorporates treatment, period and carryover effects.
 - ii) Assess the evidence that there is a carryover effect from period 1 to period 2.
 - iii) Do the data provide evidence that there is a difference in average response between periods 1 and 2?
 - iv) Assess whether the treatments differ in effect, taking into account the results of your assessments of carryover and period effects.
 - v) Repeat the statistical analysis in R
 - vi) ★The final stage in the analysis recorded below produced 95% Confidence Intervals, firstly, for the mean differences in response between periods 1 and 2 for the 21 subjects and, secondly, for the mean differences in response to treatments A and B for the 21 subjects. By referring to your model for these data, explain why these two confidence intervals can **not** be used to provide indirect tests of the hypotheses of no period and no treatment effects respectively.



Extract from SPSS Analysis of Crossover Trial on Liver Treatment

Summarize

Case Summaries(a)

Patnum	Group	Period1	Period2	Sum1+2	PeriodDiff	TreatDiff
1.00	1.00	48.00	51.00	99.00	-3.00	-3.00
2.00	1.00	43.00	47.00	90.00	-4.00	-4.00
3.00	1.00	60.00	66.00	126.00	-6.00	-6.00
4.00	1.00	35.00	40.00	75.00	-5.00	-5.00
5.00	1.00	36.00	39.00	75.00	-3.00	-3.00
6.00	1.00	43.00	46.00	89.00	-3.00	-3.00
7.00	1.00	46.00	52.00	98.00	-6.00	-6.00
8.00	1.00	54.00	42.00	96.00	12.00	12.00
9.00	2.00	31.00	34.00	65.00	-3.00	3.00
10.00	2.00	51.00	40.00	91.00	11.00	-11.00
11.00	2.00	31.00	34.00	65.00	-3.00	3.00
12.00	2.00	43.00	36.00	79.00	7.00	-7.00
13.00	2.00	47.00	38.00	85.00	9.00	-9.00
14.00	2.00	29.00	32.00	61.00	-3.00	3.00
15.00	2.00	35.00	44.00	79.00	-9.00	9.00
16.00	2.00	58.00	50.00	108.00	8.00	-8.00
17.00	2.00	60.00	60.00	120.00	.00	.00
18.00	2.00	82.00	63.00	145.00	19.00	-19.00
19.00	2.00	51.00	50.00	101.00	1.00	-1.00
20.00	2.00	49.00	42.00	91.00	7.00	-7.00
21.00	2.00	47.00	43.00	90.00	4.00	-4.00

T-Test

Independent Samples Test

	Mean Difference	Std. Error Difference	t	Df	Sig. (2-tailed)
Sum1+2	2.7308	8.7046	.314	18.683	.757
PeriodDiff	-5.9423	2.9429	-2.019	17.646	.059
TreatDiff	1.4423	2.9429	.490	17.646	.630



Summarize

Case Summaries(a)

			Summ1+2	PeriodDiff	TreatDiff
GROUP	1.00	1	99.00	-3.00	-3.00
		2	90.00	-4.00	-4.00
		3	126.00	-6.00	-6.00
		4	75.00	-5.00	-5.00
		5	75.00	-3.00	-3.00
		6	89.00	-3.00	-3.00
		7	98.00	-6.00	-6.00
		8	96.00	12.00	12.00
	Total	N	8	8	8
		Mean	93.5000	-2.2500	-2.2500
		Std. Deviation	16.1688	5.8979	5.8979
	2.00	1	65.00	-3.00	3.00
		2	91.00	11.00	-11.00
		3	65.00	-3.00	3.00
		4	79.00	7.00	-7.00
		5	85.00	9.00	-9.00
		6	61.00	-3.00	3.00
		7	79.00	-9.00	9.00
		8	108.00	8.00	-8.00
		9	120.00	.00	.00
		10	145.00	19.00	-19.00
11		101.00	1.00	-1.00	
12		91.00	7.00	-7.00	
13		90.00	4.00	-4.00	
Total	N	13	13	13	
	Mean	90.7692	3.6923	-3.6923	
	Std. Deviation	23.6684	7.4876	7.4876	
Total	N	21	21	21	
	Mean	91.8095	1.4286	-3.1429	
	Std. Deviation	20.7235	7.3863	6.8065	

Explore

		Lower Bound	Upper Bound
PeriodDiff	95% Confidence Interval for Mean	-1.9336	4.7908
TreatDiff	95% Confidence Interval for Mean	-6.2411	-0.044571



- 2) Several studies have considered the relationship between elevated blood glucose levels and occurrence of heart problems. The results of two similar studies are summarized below.

glucose level	Study 1			Study 2		
	heart problems			heart problems		
	yes	no		yes	no	
elevated	61	1284	1345	32	996	1028
not elevated	82	1930	2012	25	633	658
	143	3214	3357	57	1629	1686

- i) What can be concluded from these data regarding the influence of glucose on heart problems?
- ii) Do you have any doubts on the validity of the form of analysis you have used?
- 3) A randomized, parallel group, placebo controlled trial was undertaken to assess the effect on children of a cream in reducing the pain associated with venepuncture at the induction of anaesthesia. A binary response of $Y=0$ for 'did not hurt' and $Y=1$ for 'hurt' was recorded for each of the 40 children who entered the trial, together with the treatment given (x_1) and two covariates, sex (x_2) and age (x_3), which were thought might affect pain levels. A logistic model was fitted and the following details are available.

Factor	Reg. Coeff.	Standard Error of Coefficient
Intercept	2.058	1.917
x1: treatment (0 = placebo, 1 = cream)	-1.543	0.665
x2: sex (0 = boy, 1 = girl)	0.609	0.872
x3: age (years)	-0.461	0.214



- i) Interpret and assess the treatment effect and also the effects of sex and age.
 - ii) Estimate the relative risk of hurting with the cream compared to the placebo.
- 4) Returning to the Australian study on survival of spoons,
- i) Is there evidence that the disappearance of spoons is dependent upon either the category of tearoom or the value of the spoon?
 - ii) What is the average rate of loss of teaspoons?
 - iii) If the Institute where the study was conducted has 150 employees, how many teaspoons should be purchased annually to provide one spoon for every two people?

