Master in Pharmacy

Introductory Course in Applied Biostatistics in Clinical Research

EXERCISES: Hypothesis Testing

1. The body temperature data set DataP4.txt contains the body temperature (Fahrenheit) and the gender of 130 volunteers, 65 men and 65 women. Answer the following question justifying the distributions considered to perform the tests.

   (a) Is the mean body temperature of women higher than the mean body temperature of men?

   (b) Construct a 90% confidence interval for the difference of means for both genders. Use this interval to test the hypothesis of the difference of mean values $(\mu_{women} - \mu_{men})$ being equal to one.

2. During an experiment using laboratory animals the following data on renal corticol blood flow (ml/g/min) during control conditions and during the administration of a certain anesthetic were recorded.

Animal Number	Control	Anesthetic	Animal Number	Control	Anesthetic
1	2.35	2.00	9	2.58	2.10
2	2.55	1.71	10	2.66	2.58
3	1.95	2.22	11	2.31	1.32
4	2.79	2.71	12	3.43	3.70
5	3.21	1.83	13	2.37	1.59
6	2.97	2.14	14	1.82	2.07
7	3.44	3.72	15	2.98	2.15
8	2.53	2.05			

   (a) Can one conclude on the basis of these data that the anesthetic retards renal corticol blood flow?

1

3. Nurses in an inner-city hospital were unknowingly observed on their use of latex gloves during procedures for which glove use is recommended. The nurses then attended a presentation on the importance of glove use. One month after the presentation, the same nurses were observed again. Here are the proportions of procedures for which each nurse wore gloves:

Nurse	Before	After	Nurse	Before	After
1	0.857	0.500	8	0.000	1.000
2	0.500	0.833	9	0.000	0.667
3	1.000	1.000	10	0.167	1.000
4	0.000	1.000	11	0.000	0.750
5	0.000	1.000	12	0.000	1.000
6	0.000	1.000	13	0.000	1.000
7	1.000	1.000	14	1.000	1.000

(a) Why is a one-sided alternative proper here? Why must matched pairs methods be used?

(b) Does the test indicate that the presentation was helpful? Use an adequate hypothesis testing after verifying the assumptions.

(c) Find the 90% confidence interval.

4. A study investigated the effect of codeine on gastrintestinal motility (Mikus *et al.*, 1997). Of interest was determine whether or not problems associated with motility are due to the codeine or its metabolite morphine. The study had both a crossover phase and a parallel phase, and was made up of five subjects who are extensive metabolizers and five who are poor metabolizers.

Extensive			Poor		
Codeine	Placebo	$D = C - P$	Codeine	Placebo	$D = C - P$
13.7	7.2	6.5	13.7	11.7	2.0
10.7	4.7	6.0	7.7	6.7	1.0
8.2	5.7	2.5	10.7	6.2	4.5
13.7	10.7	3.0	8.7	6.2	2.5
6.7	6.2	0.5	10.7	11.7	−1.0
	$\bar{d} = 3.7 \ s_d = 2.51$			$\bar{d} = 1.8 \ s_d = 2.02$	

(a) In one phase of the study, the researchers measured the orocecal transit times (OCTT in hrs) after administration of placebo and after 60 mg codeine phosphate in healthy volunteers. Data are given in Table. Test whether or not their is an increase in motility time while on codeine as compared to on placebo separately for each metabolizing group. Use the paired t-test and $\alpha = 0.05$. Intuitively, do you feel this implies that codeine, or its metabolite morphine may be the cause of motility, based on these tests?

(b) In a separate part of the study, they compared the distributions of maximum concentration (Cmax) of both codeine and its metabolite morphine. Use the independent sample t-test to compare them.

5. Orlistat, an inhibitor of gastrointestinal lipases has recently received FDA approval as treatment for obesity. Based on its pharmacologic effects, there are concerns it may interact with oral contraceptives among women. A study was conducted to determine whether progesterone or luteinizing hormone levels increased when women were simultaneously taking orlistat and oral contraceptives versus when they were only taking contraceptives (Hartmann *et al.*, 1996). For distributional reasons, the analysis is based on the natural log of the measurements, as opposed to their actual levels. The data and relevant information are given in next Table for the measurements based on progesterone levels $(\mu g l^{-1})$.

(a) Can we determine that levels of the luteinizing hormone are higher among women receiving orlistat than women receiving placebo?

(b) Conduct the same hypothesis test based on the pairedât test at $\alpha = 0.05$

(c) Should women fear that use of orlistat decreases the efficacy of oral contraceptives (in terms of increasing levels of luteinizing hormones)?

Subject	Orlistat	Placebo
1	0.5878	0.5653
2	0.3646	0.3646
3	0.3920	0.3646
4	0.9243	1.3558
5	0.6831	1.0438
6	1.3403	2.1679
7	0.3646	0.3646
8	0.3646	0.3646
9	0.4253	0.8329
10	0.3646	0.3646
11	0.3646	0.3646
12	0.3646	0.3646
13	1.6467	1.4907
14	0.3646	0.3646
15	0.5878	0.4055
16	0.3646	0.3646
17	0.5710	0.4187
18	1.1410	1.4303
19	1.0919	0.7747
20	0.7655	0.3646
Mean	0.654	0.707
Std Dev	—	—