

MUSC WEIGHT MANAGEMENT CENTER CLINICAL TRIALS EXPERIENCE (Rev. 12/6/11; 3 pages)

SPONSOR	YEAR	LENGTH OF TRIAL	# ENROLLED (PASSED SCREENING)	# GOAL	RETENTION	# OF SITES	SUBJECT CHARACTERISTICS AND SPECIAL CONSIDERATIONS OF THE TRIAL
#19	2011	164 weeks	23	20	Ongoing	170	Subjects: Pre-diabetic and non pre-diabetic with BMI ≥ 30 or ≥ 27 in the presence of co-morbidities (treated or untreated hypertension or dyslipidaemia)
#18	2009	12 weeks	132	120	112	1	Subjects: BMI 27-35. Non-medication trial comparing two diet plans. 156 screened. Original enrollment goal was 120 in 3 months; accomplished enrollment was 132 in 2 months. Single-site trial.
#16	2007	52 weeks	6	30	2	750	Subjects: BMI 27-45 with type II diabetes that is controlled with medication and generally healthy.
#16	2007	52 weeks	30	30	23	100	Subjects: Generally healthy obese men and women BMI 30-45. <i>73 screened in 3 months</i>
#15	2007	56 weeks	94	89	70	9	Subjects: Generally healthy obese men and women (BMI 30-45). Protocol includes <i>year-long group-based behavioral weight loss program</i> for all subjects + investigational medication. <i>133 screened in < 7 months.</i>
#17	2007	224 weeks	14	40	Ended early by sponsor	10	Subjects: Phase IIB. BMI 30-45. Near-weekly visits during first phase with fasting blood draws, PK studies, demanding subject recording requirements.
#16	2006	104 weeks	27	30	6 completed year 2	100	Subjects: Generally healthy obese men and women (BMI 30-45); Clean echocardiogram required in screening. <i>49 consented and screened in < 2 months</i>
#12	2006	24 weeks	4	8	3	40	Subjects: Men and women with elevated waist circumference and dyslipidemia
#15	2006	52 weeks	38	41	24	15	Subjects: Generally healthy obese adults (BMI 30-43), 18-60 years old, non-smoker. <i>48 consented and screened in < 3 months</i>
#14	2005	108 weeks	31 (25 women; 16 men)	30 (24 women; 16 men)	Cancelled by sponsor after 1 year extension added to protocol	148	Subjects: Obese men and women (BMI >30 , > 27 with specified co-morbidities) with at least one risk factor associated with metabolic syndrome. <i>40% of subjects required to be males.</i> Demanding eligibility criteria based on screen assessments. <i>73 consented and screened in three months.</i>
#15	2005	52 weeks	49	49	31	7	Subjects: Generally healthy obese adults (BMI 30-40), 18-60 years old, non-smoker. Ancillary eating behavior study.
#12	2004	6 months	12	8	7	20	Subjects: Generally healthy obese adults (BMI 30-45) with binge eating disorder, no clinically significant disease or history of other eating disorders
#15	2004	48 weeks	24	24	13	5	Subjects: Generally healthy obese adults (BMI 30-40), 18-60 years old, non-smoker. <i>Enrollment completed in 3 weeks.</i>

#15	2003	48 weeks	21	40	Cancelled by sponsor	8	Subjects: Generally healthy obese adults (BMI 30-40), 18-60 years old, non-smoker. Recruitment closed early (8 weeks).
#14	2003	58 weeks	22	14	11	25	Subjects: Obese adults (BMI 30-43), generally healthy. 6-week VLCD followed by randomization to drug/placebo for 1-yr maintenance. 42 screened in relatively short period.
#4	2003	6 months	26	26	21	29	Subjects: Mildly overweight (BMI 25-28), healthy adults. Study drug with likelihood of initial gastrointestinal side effects. 47 screened.
#13	2002	6 months	4	8	1	17	Subjects: Generally healthy obese (BMI > 30) adults with low-prevalence syndrome (primary insulin hypersecretion) screened via OGTT. 67 screened. Injectable medication. Two of three dropouts due to side effects.
#12	2001	108 weeks	40	40	22 at year 1 7 at year 2	72	Subjects: Adults BMI > 30 or 27-30 with co-morbidities, otherwise generally good health. Compliance during 4-week run-in required for randomization. 5-month enrollment period. 71 screened.
#4	2000	52 weeks	30	25	14	28	Subjects: Adolescents BMI 2 units above 95 th age-sex %ile. Ages 12-16, generally good health. Study drug with a high likelihood of initial gastrointestinal side effects.
#11	2000	26 weeks	35	25	24	14	Subjects: BMI 27-50, 18-75 years of age; generally good health. Phase II study. 4 dosages active medication and placebo. 24-week double-blind placebo-controlled treatment phase, 4-week followup phase. Quota raised to 35 based on success. Consented and screened 49.
#10	2000	50 weeks	53	50	29	6	Subjects: BMI 30-44; 18-65 years of age; generally good health; phase IV. Two week diet run-in, 24-week double blind study followed by a 24-week active treatment phase. Consented and screened 75.
#9	2000	108 weeks	34	40	Cancelled by sponsor	25	Subjects: BMI 30-45; 18 years of age or older; generally good health; phase III study. Four week run-in, 52-week double blind study followed by a 52-week open label extension. Consented and screened 50.
#8	2000	26 weeks	30	45	22	12	Subjects: BMI 30-40; 18-65 years of age; generally good health; phase II study. Subjects assigned to one of five treatment arms. Recruitment limited to 7-week period. Consented and screened 44. Higher than predicted screen fail rate.
#5	1999	26 weeks	14 ^A	open	12	17	Subjects: BMI 27.5-38.0; generally good health; subjects required to self-inject study drug; entry into trial dependent on blood screen results ruling out more than 90% of applicants nationally; phase II; short recruitment period
#4	1998	52 weeks	12	12	4	40	Subjects: Type 2 diabetics inadequately controlled on metformin; BMI 28-43; phase IIIb. Study drug with a high likelihood of initial gastrointestinal side effects. Low retention

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#5	1998	104 weeks	11	16	Cancelled by sponsor	22	Subjects: Completers of prior 32-week double-blind placebo controlled trial (below); open label trial; phase II
#4	1996	19 and 23 month follow-ups	NA	19 eligible for follow-up	19 followed	90	Subjects: Females 45 years of age or older (at the time of randomization) who were treated in previous trial sponsored by #4 (76-week trial below) Two follow-up phone surveys to check health status 19 and 23 months after original trial.
#5	1997	32 weeks	25	40	16 ^B	7	Subjects: BMI 27.5-38; generally good health; subjects required to self-inject study drug BID; very short recruitment phase (38 days); phase II
#7	1997	24 weeks	35	36	14 ^C	Approx. 11	Subjects: BMI 30-40; generally good health; phase II Subjects were required to complete two 12-hour diurnal visits.
#6	1995	52 weeks	17	20	8 ^D	12	Subjects: Hypertensives well-controlled on calcium channel blockers; BMI 27-40; phase III
#5	1997	1 day per subject	60	60	60	Approx. 11	Subjects: BMI 27.5-38; protocol required a specific number of males/females per BMI subgroup
#4	1993	76 weeks	46	40	37	17	Subjects: BMI 28-38; two 3-day fecal collections required; 92 subjects entered a 6-month, non-drug, dietary lead-in phase; 46 subjects qualified (by losing $\geq 8\%$ of initial body weight) to be randomized to study drug; phase III Study drug with a high likelihood of initial gastrointestinal side effects.
#3	1990	14 weeks	28	40	14 ^E	5	Subjects: Initial BMI >35 who successfully completed a 12-week very low calorie diet in a fee-based program; phase IV
#3	1988	68 weeks	61	60	28	12	Subjects: BMI ≥ 30 (2/3 had to be BMI ≥ 35), at least a one year history of type 2 diabetes or hyperlipidemia
#2	1983	10 weeks	49	NA	36	5	Subjects: 21-60 years of age, $\geq 30\%$ overweight
#1	1988	52 weeks	NA	77 eligible for follow-up	77 followed	17	Subjects: Initially $\geq 30\%$ overweight Follow-up assessment of private patients treated with very low calorie diet ≥ 1 year previously.

A-- Final entry dependent on an abnormally low blood level of a specific protein. 157 otherwise qualified patients screened in a 2 month period, 18 passed initial screening, 14 randomized.

B--Many subjects grew tired of BID injections.

C--Many subjects were discouraged by a lack of efficacy of study medication.

D-- Non-drug interventions limited to very minimal dietary counseling

E--Trial terminated prematurely by sponsor due to recruitment difficulties at all sites.