Childhood Asthma Management Program (CAMP): Dataset for Teaching Purposes

About CAMP

The Childhood Asthma Management Program (CAMP) was a clinical trial carried out in children with asthma. The trial was designed to determine the long-term effects of 3 treatments (budesonide, nedocromil, or placebo) on pulmonary function as measured by normalized FEV1 over a 5-6.5 year period. The design of CAMP was a multicenter, masked, placebo-controlled, randomized trial. A total of 1,041 children (311 in the budesonide group, 312 in the nedocromil group and 418 in the placebo group) aged 5-12 years were enrolled between December of 1993 and September of 1995. The primary outcome of the trial was lung function as measured by the Forced Expiratory Volume at 1 second (FEV_1). Secondary outcomes included: bronchial responsiveness to methacholine, need for beclomethasone due to asthma symptoms, termination of assigned treatment due to cessation of symptoms, and as Asthma morbidity (frequency and severity of asthma symptoms, frequency and magnitude of PEFR measurements less than 80% of personal best, *prn* use of supplemental inhaled albuterol, nocturnal awakenings, days of limited activity, and absences from school, courses of steroids). The Study also followed participants for outcomes related to mortality, long term safety, side effects, physical growth and development, psychological growth and development, individual and family functioning, and use of health care resources.

Main trial results: There was no significant difference between the intervention treatments and placebo in the primary outcome, FEV_1 after the administration of a bronchodilator. As compared with the children assigned to placebo, the children assigned to receive budesonide had a significantly smaller decline in the ratio of FEV_1 to forced vital capacity (FVC, expressed as a percentage) before the administration of a bronchodilator (decline in FEV_1:FVC, 0.2 percent vs. 1.8 percent). The children given budesonide also had lower airway responsiveness to methacholine, fewer hospitalizations (2.5 vs. 4.4 per 100 person-years), fewer urgent visits to a caregiver (12 vs. 22 per 100 person-years), greater reduction in the need for albuterol for symptoms, fewer courses of prednisone, and a smaller percentage of days on which additional asthma medications were needed. As compared with placebo, nedocromil significantly reduced urgent care visits (16 vs. 22 per 100 person-years) and courses of prednisone. The mean increase in height in the budesonide group was 1.1 cm less than in the placebo group (22.7 vs. 23.8 cm, P=0.005); this difference was evident mostly within the first year. The height increase was similar in the nedocromil and placebo groups.

Post Trial : The CAMP Continuation Study (CAMP-CS) extended follow-up for 941 participants for an additional 4.5 years to determine the effects of 3.5-5.5 years of anti-inflammatory treatment administered early in childhood on the time course of the progression of asthma through puberty as indicated by lung development, physical growth, and bone density; by the pattern of bronchial reactivity; by the occurrence, relapse, and remission of asthma symptoms; by the use of asthma medications; by the need for health care services; and by self-reported quality of life. Follow-up has been further extended through the second and third continuation studies.

Dataset for Teaching Purposes

The primary purpose of the CAMP based teaching dataset is for statistical analysis of repeated measures; however, this can be expanded to include working with missing data, mixed models, and measures of association between baseline values and follow-up measures. The data is provided in SAS version 9 format (camp_teach.sas7bdat), STATA format (camp_teach.sav), SPSS format (camp_teach.dta), Excel format (camp_teach.xlsx), and a comma separated variable file (camp_teach.csv).

The dataset was not prepared to reproduce primary outcome results. A number of techniques were employed to completely anonymize the data. Most variables were permuted over the set of participants within a treatment group with one variable being permuted without regard to treatment allocation. After permutation of selected variables, a random sample of approximately 2/3 of the 1041 participants was then selected for inclusion in the teaching dataset. **Thus, it would be inappropriate to use this dataset for any research or publication purposes regarding possible inferences.**

Dataset Variables

Variable	Type	Len	Format	Label
TX	Char	4		Treatment group: bud,ned,pbud,or pned
TG	Char	1		Treatment group: A=bud, B=ned, C=plbo
id	Num	8		Randomized participant ID
age_rz	Num	8		Age in years at Randomization
GENDER	Char	1		m=male, f=female
ETHNIC	Char	1		w=white,b=black,h=hispanic,o=other
hemog	Num	8		Hemoglobin (g/dl)
PREFEV	Num	8	BEST12.	PreBD FEV1
PREFVC	Num	8	BEST12.	PreBD FVC
PREFF	Num	8	BEST12.	PreBD FEV1/FVC ratio %
PREPF	Num	8	BEST12.	PreBD peak flow
POSFEV	Num	8	BEST12.	PostBD FEV1
POSFVC	Num	8	BEST12.	PostBD FVC
POSFF	Num	8	BEST12.	PostBD FEV1/FVC ratio %
POSPF	Num	8	BEST12.	PostBD peak flow
PREFEVPP	Num	8	BEST12.	PreBD FEV1 %pred
PREFVCPP	Num	8	BEST12.	PreBD FVC %pred
POSFEVPP	Num	8	BEST12.	PostBD FEV1 %pred
POSFVCPP	Num	8	BEST12.	PostBD FVC %pred
wbc	Num	8		White Blood Cell count (1000 cells/ul)
agehome	Num	8		Age of current home (years)
anypet	Num	8		Any pets, 1=Yes 2=No
woodstove	Num	8		Used wood stove for heating/cooking, 1=Yes 2=No
dehumid	Num	8		Use a dehumidifier, 1=Yes 2=No 3=DK
parent_smokes	Num	8		Either Parent/partner smokes in home, 1=Yes 2=No
any_smokes	Num	8		Anyone (including visitors) smokes in home, 1=Yes 2=No
visitc	Char	3		Followup Visit (mos)
fdays	Num	8		Days since randomization

Notes: [Bud] Inhaled glucocorticoid (budesonide), [Ned] Inhaled nonsteroidal anti-inflammatory (nedocromil), [Plbo] Placebo (albuterol) = [pbud]: budesonide placebo or [pned]: nedocromil placebo

- PreBD, PostBD=Pre- or post-bronchodilator

Tables

Characteristics by Treatment Group at Randomization

	Treatment group: A=bud, B=ned, C=plbo											
	A				B				C			
	N	Mean	Std	Median	N	Mean	Std	Median	N	Mean	Std	Median
Age in years at Randomization	210	8.51	2.137	8.00	210	8.30	2.166	8.00	275	8.33	2.171	8.00
Hemoglobin (g/dl)	206	13.11	1.272	13.10	208	13.11	1.291	13.10	273	13.15	0.946	13.20
White Blood Cell count (1000 cells/ul)	208	73.65	22.027	71.00	209	74.76	23.941	71.00	274	73.54	22.087	71.00
Age of current home (years)	202	32.73	26.479	25.00	208	30.55	26.836	22.50	269	34.18	25.273	30.00
PreBD FEV1	210	1.66	0.450	1.61	210	1.60	0.484	1.54	274	1.67	0.500	1.60
PreBD FVC	210	2.13	0.606	2.09	210	2.03	0.628	1.94	274	2.10	0.652	2.01
PreBD FEV1/FVC ratio %	210	78.91	8.722	80.00	210	79.34	7.681	80.00	274	80.05	8.224	80.00
PreBD peak flow	208	277.02	65.464	280.00	207	268.47	69.582	265.00	268	275.75	70.483	275.00
PostBD FEV1	210	1.85	0.484	1.79	210	1.75	0.513	1.69	274	1.83	0.528	1.75
PostBD FVC	210	2.18	0.620	2.12	210	2.06	0.629	1.94	274	2.14	0.665	2.06
PostBD FEV1/FVC ratio %	210	85.22	6.676	86.00	210	85.24	6.154	86.00	274	85.95	6.316	86.00
PostBD peak flow	209	304.62	64.609	305.00	206	291.29	70.594	285.00	268	299.07	68.287	300.00
PreBD FEV1 %pred	208	92.51	14.341	92.00	207	92.99	14.691	93.00	271	94.50	13.501	94.00
PreBD FVC %pred	208	103.46	12.807	103.00	207	103.94	13.857	104.00	271	104.26	12.862	103.00
PostBD FEV1 %pred	208	102.63	12.958	103.00	207	102.01	13.377	101.00	271	103.59	12.139	104.00
PostBD FVC %pred	208	106.33	12.915	105.50	207	106.07	12.944	106.00	271	106.41	12.522	106.00

Characteristics by Treatment Group at Randomization (cont'd)

	Treatment group: A=bud, B=ned, C=plbo		
	A	B	C
	%	%	%
Female	40.0	33.3	46.9
Race/Ethnicity			
Black	12.9	12.9	12.7
Hispanic	9.5	11.0	9.1
Other	10.0	8.1	7.6
White	67.6	68.1	70.5
Any pet in home	69.0	71.9	69.5
Used Woodstove for heating/cooking	7.1	8.6	9.1
Used dehumidifier	5.2	10.5	9.5
Either parent or partner smokes in home	28.6	26.7	29.1
Anyone in home smokes	31.0	28.1	30.9

Number of spirometry measures

	Treatment group: A=bud, B=ned, C=plbo		
	A	B	C
	%	%	%
1 – 6	3.34	4.29	3.63
7 – 10	6.67	4.76	6.17
11 - 14	25.24	25.72	22.92
15 - 16	56.19	58.10	57.46
17 - 18	8.57	7.14	9.82

Form components used in the Teaching Dataset

Home Environment Questionnaire

Purpose: To describe the child's home environment and provide data for environmental counselling.

When: Visits S1 (assigned to visit RZ in teaching dataset), F12, F24, F36, F48, F60, F72.

Administered by: Caretaker and coordinator.

Respondent: Caretaker who lives with the child.

Instructions: Caretaker: complete this form at home and bring it to your next visit. If you check a check space that is connected to a box with a number in it, you may skip to that item, leaving items in between blank (for example, if you check "No" to item 12, you may skip to item 16). **Coordinator:** mail this form to the caretaker 2 weeks prior to the annual followup visit; review the form with the caretaker for questions that were not understood.

11. About how old is your current home *(estimate if uncertain):*

AGEHOME

____ years

17. During the past year...

a. Have you used a wood stove to heat your home or to cook on:

WOODSTOVE

1 2

18.

b. Hours per week: _____ ____ ____

hrs/wk

...

e. (

28. Do you use a dehumidifier: *(include dehumidifier built into your heating system; check only one):*

Yes (1)

No (2)

Don't know (3)

DEHUMID

____ ____

number

51. Do you currently smoke cigarettes:

Yes (1) No (2)

54.

59. Not counting yourself, your partner and this child, does anyone else smoke cigarettes inside your home (include visitors, such as grandparents or babysitters, who visit at least 5 times per week):

ANY_SMOKES

Yes (1) No (2)

61. ____

55. Is there another primary adult (for example, your spouse or partner) living in your household:

Yes (1) No (2)

59. ____

56. Does that person currently smoke cigarettes:

Yes (1) No (2)

58. ____

60. Do you have any pets: **ANYPET**

(1) (2)

65. ____

PARENT_SMOKES

If respondent smokes (q51=1) or [another primary adult (q55=1) and that person smokes (q56=1)] then parent_smokes=1;

If respondent does not smoke (q51=2) and [no other primary adult (q55=2) or [another primary adult (q55=1) and that person does not smoke (q56=2)]] then parent_smokes=2;

Purpose: Record results of hematology laboratory assessments.

When: Visits S3 (assigned to visit RZ for teaching dataset) and F48.

Completed by: Center coordinator. **Respondent:** None.

Instructions: Request a CBC, manual differential, and total eosinophil count. Ask your lab to report exact levels, not that a level is within a range. Extract values from report returned by your laboratory. If a value is missing from the report returned by your lab, enter "m" for the missing value. Please note that the units 10^3 cells/ μl, 1000 cells/ μl, and 10^9 cells/L are equivalent. Staple the lab report to the back of this form. If your lab reports values electronically, print a copy of the results and staple the print out to the back of this form.

A. Hematology

7. White blood cell count (WBC):

WBC

____ ____ ____ ____

10^3 cells/ μl or 10^9 cells/L

8. Hemoglobin

a. Value: ____ HEMOG ____

b. Units *(check only one):*

g/dl (1)

g/L (2) – transformed to g/dl

Pulmonary Function

256

Purpose: To document spirometry and peak flow results.

When: Visit RZ, F2, F4, F12, F16, F24, F28, F36, F40, F48, F52, F60, F64, F72, F76 (ie, at all visits at which the methacholine challenge is not performed.)

Administered by: Pulmonary function technician.

Respondent: Child.

Instructions: You must measure height according to Protocol before proceeding with spirometry; obtain standing height from Form PE or PP for this visit. **If a STOP condition is checked**, do not do spirometry until the specified amount of time has passed. If the patient cannot wait the needed time, do not do spirometry, but complete Section D. Set the partially completed Form PF aside until the rescheduled visit. Complete a new Form PF (all items) at the rescheduled visit. Staple the partially completed Form PF to the new Form PF. **If spirometry is completed at the RZ visit, but the efforts are not reproducible or effort is poor**, do not randomize the child. STOP the visit and reschedule visit RZ. **If spirometry is not completed but this is not visit RZ**, obtain the pre and post bronchodilator peak flow values and complete as much of Form PF as possible. Set the partially completed Form PF aside. Reschedule spirometry within the visit window. Complete a new Form PF (all items) at the rescheduled visit. Staple the partially completed Form PF to the new Form PF. Key only the new Form PF after the rescheduled visit. Update the child's Best Pre-Bronchodilator FEV_1 Log if the pre- bronchodilator FEV_1 at this visit is larger than the previous best value. If the post-bronchodilator peak flow obtained at this visit is higher than the child's previous personal best, update the child's Personal Best Peak Flow Log. Affix labels to the tracings and staple the spirometry report and tracings to this form.

A. Spirometry

9. Was spirometry completed:

Yes (+ 1) No (* 2)

14. ___

+ If spirometry was completed at the RZ visit BUT the tests were not reproducible or there was poor effort, or spirometry was otherwise unsuccessful even though the session was completed, STOP. Do not randomize the child. Reschedule visit RZ.
** Reschedule spirometry within the visit window.*

13. Reason spirometry was not completed *(check all that apply):*

a. Unable to cooperate (* 1)

b. Other *(specify):* (* 1)

_____
specify

** Complete items 19, 22-27, pre and post peak flows and administrative information*

14. Spirometer identification number:

____ ____ ____ – s p i – ____ ____

a. 15. Pre-bronchodilator FVC: ___ . __ **PREFVC**
liters

16. Pre-bronchodilator FEV_1: ____ . __ **PREFEV**
liters

Record this value on the child's Best Pre-Bronchodilator FEV_1 Log if this value is larger than the previous best value.

17. Pre-bronchodilator FEV_1% predicted:

PREFEVPP
___ %

18. Pre-bronchodilator FEV_1/FVC ratio:

PREFF
___ ___ ___
%

Spirometry Measures not on the form:
POSFF (Post bronchodilator FEV_1/FVC)
PREFVCPP (Pre-bronchodilator FVC % pred)
POSFEVPP (Post-bronchodilator FEV_1 % pred)
POSFVCPP (Post-bronchodilator FVC % pred)

19. Pre-bronchodilator peak flow:

a. Size of peak flow meter *(check only one):*

Standard (1)
Low range (2)

b. 1st peak flow: ___ ___ ___
liters/min

c. 2nd peak flow: ___ ___ ___
liters/min

d. 3rd peak flow: **PREPF** ___ ___ ___
liters/min

Wait 15 minutes after administering bronchodilator before making the post-bronchodilator measurements.

20. Post-bronchodilator FVC: **POSFVC** ____ . ____
liters

21. Post-bronchodilator FEV_1: **POSFEV** ____ . ____ ____ ____
liters

22. Post-bronchodilator peak flow:
Size of peak flow meter *(check only one):*

Standard (1)
Low range (2)

b. 1st peak flow: ___ ___ ___
liters/min

c. 2nd peak flow: ___ ___ ___
liters/min

d. 3rd peak flow: ___ ___ ___
liters/min

e. In your judgment, was the child's technique acceptable:

Yes (1) No (* 2)

22f. ___ **23.** ___

*** Explain:**

_____

f. Best of the 3: **POSPF** ___ ___ ___
liters/min

If the value in item f. is larger than the child's previous personal best peak flow value, record this value on the child's Personal Best Peak Flow Log and revise the child's action plan and Diary Card Reference Values.