

Additional file.

Sample size calculation:

We used <http://www.openepi.com/SampleSize/SSMean.htm>

The calculation assumes normal distribution.

We assumed that the standard deviation of temperature measurements was 0.65 °C in accordance with formerly published results. <https://www.ncbi.nlm.nih.gov/pubmed/15502654>

We aimed at a sample size of minimum 99 children within each of the six age groups to be able to detect a minimum mean difference of +/- 0.3 °C with a standard deviation of 0.65 °C between the rectal and the alternative measurement, a 90% power, and a significance level of 0.05.

Calculation:

The screenshot shows the OpenEpi website interface. On the left is a navigation menu with categories like 'Info and Help', 'Counts', 'Person Time', 'Continuous Variables', 'Sample Size', 'Power', 'Random numbers', 'Searches', and 'Development'. The 'Sample Size' category is expanded, and 'Mean Difference' is selected. The main content area has tabs for 'Start', 'Enter', 'Results', 'Examples', and 'Help'. The 'Results' tab is active, displaying the following information:

Sample Size For Comparing Two Means

Input Data

Confidence Interval (2-sided)	95%
Power	90%
Ratio of sample size (Group 2/Group 1)	1

	Group 1	Group 2	Difference*
Mean			0.3
Standard deviation	0.65	0.65	
Variance	0.4225	0.4225	

Sample size of Group 1	99
Sample size of Group 2	99
Total sample size	198

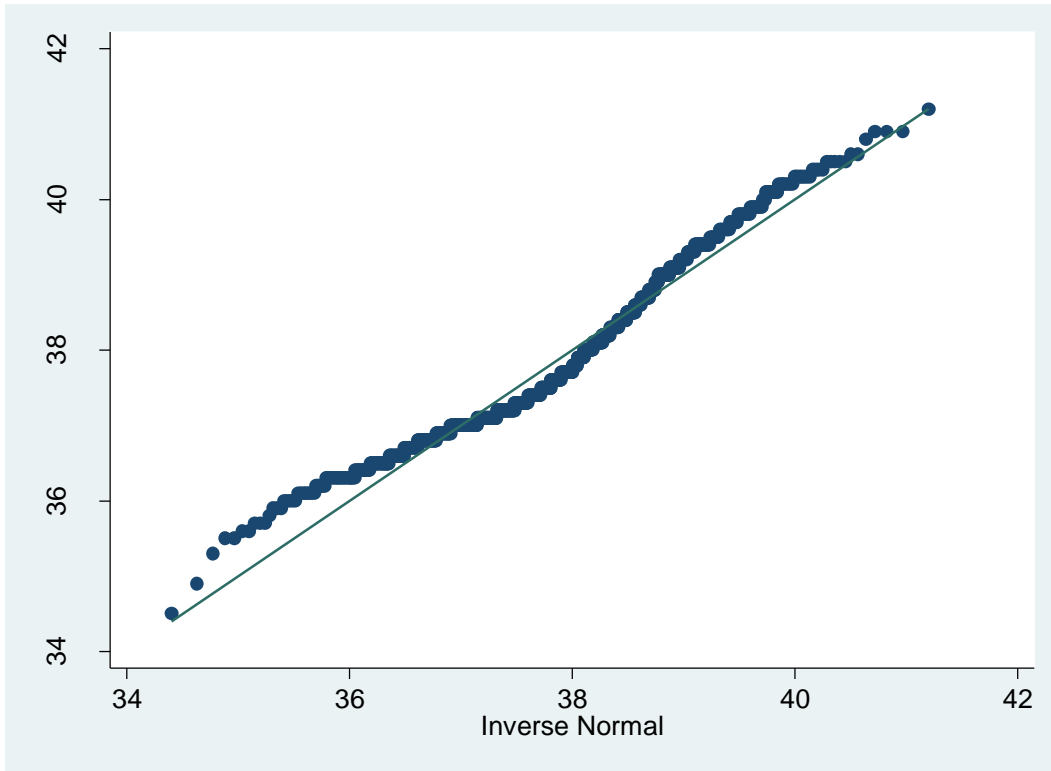
*Difference between the means

Results from OpenEpi, Version 3, open source calculator--SSMean
Print from the browser with ctrl-P
or select text to copy and paste to other programs.

Our results of the study confirmed the assumption of normal distribution within all groups of children.

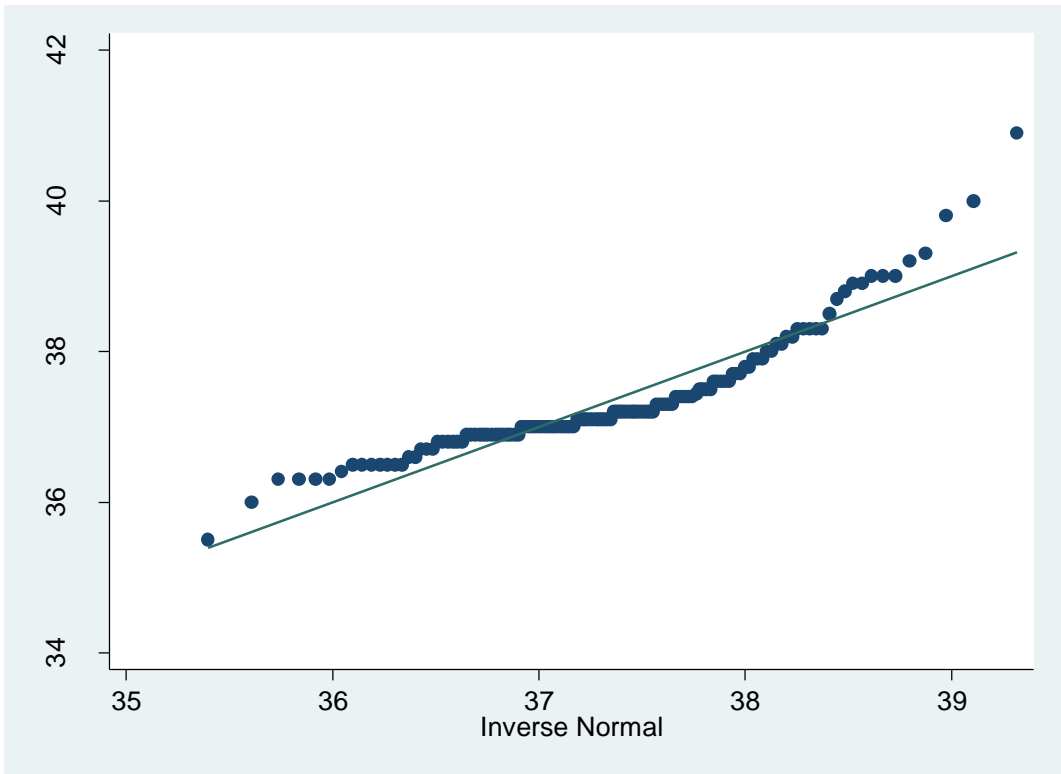
We used STATA 14. Qnorm function to assess this:

Total cohort:

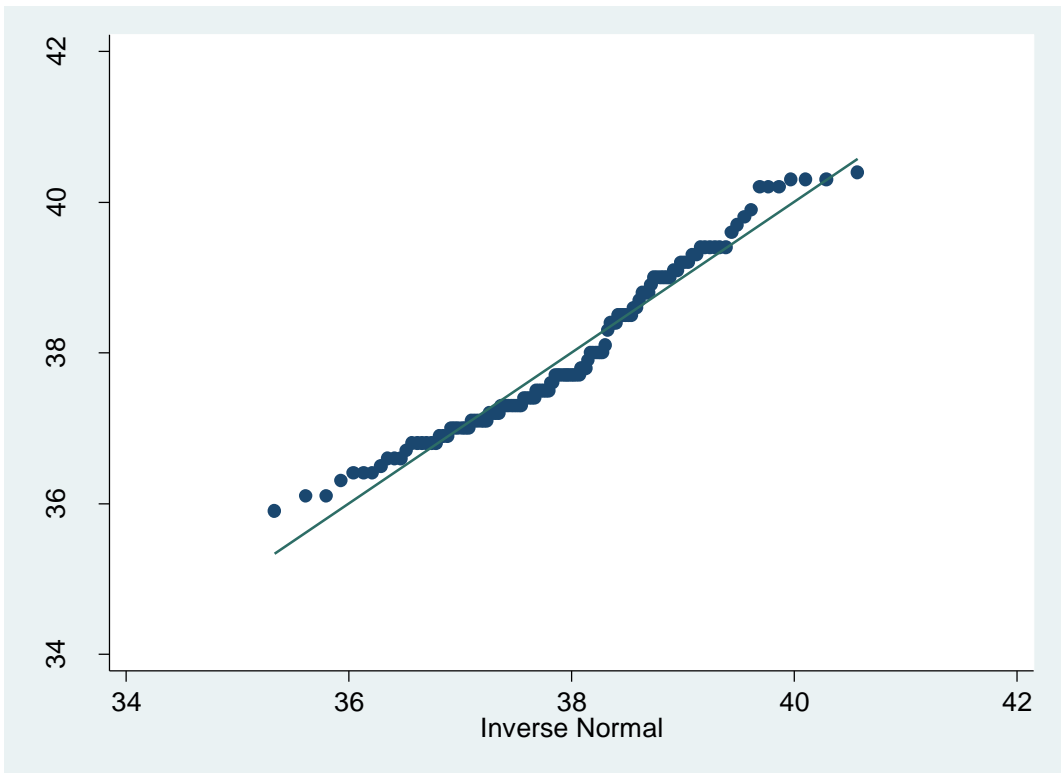


Agegroup

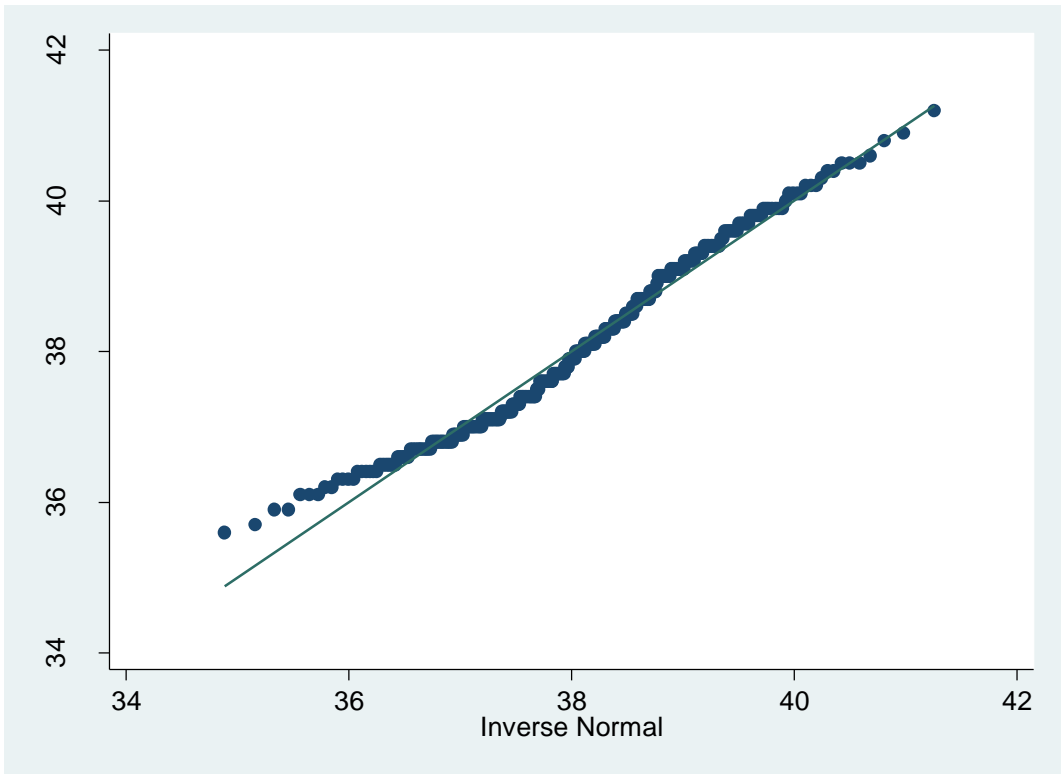
0-5 months



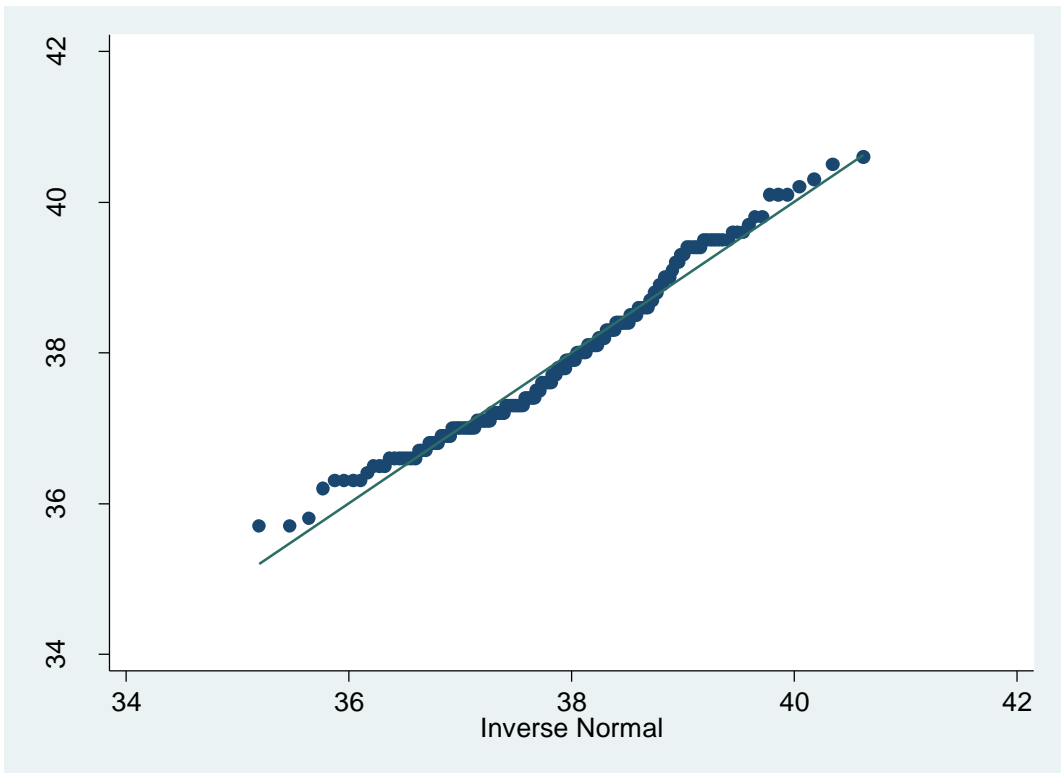
6-11 months



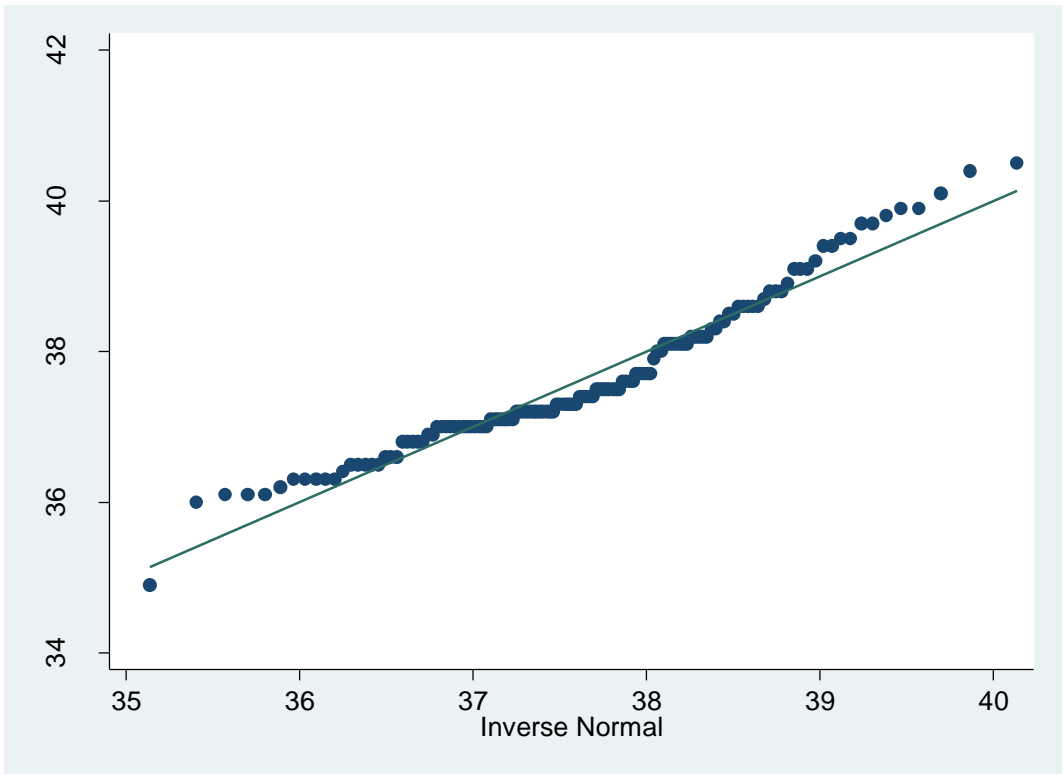
12-35 months



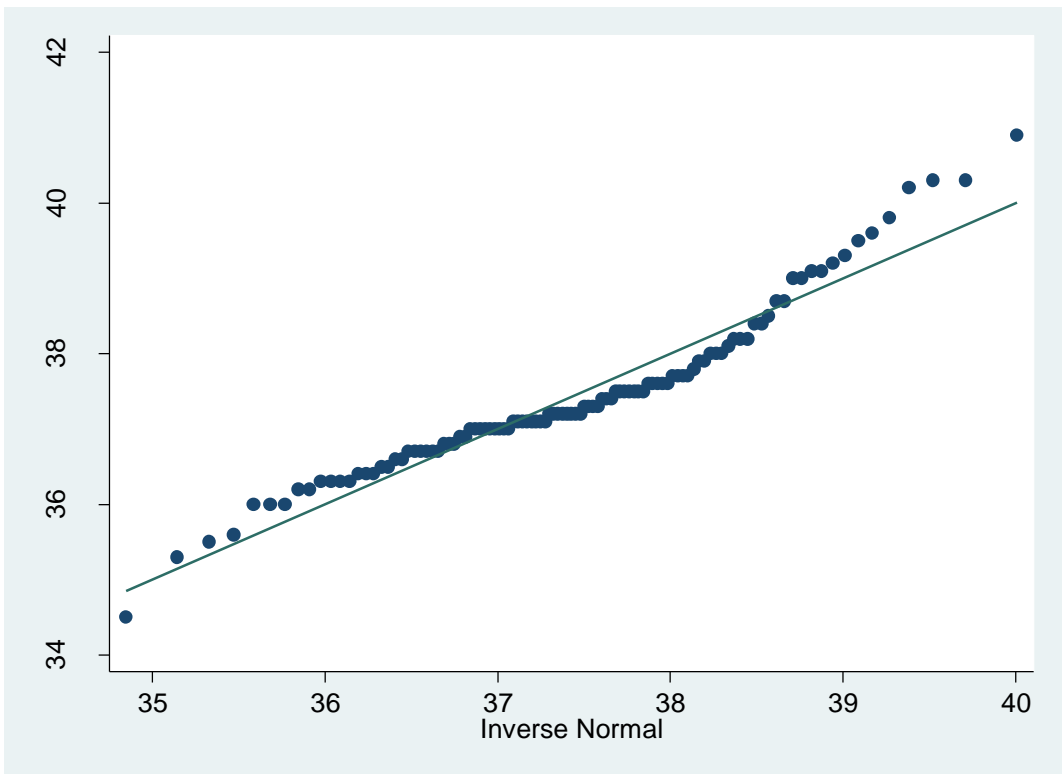
3-5 years



6-11 years



12-18 years



We assumed a SD of 0.6 °C.

Our results showed a SD of around 1.0 for the different age groups:

```
. sum tprectal if agegrp == 1
```

Variable	Obs	Mean	Std. Dev.	Min	Max
tprectal	136	37.35618	.8024057	35.5	40.9

```
. sum tprectal if agegrp == 2
```

Variable	Obs	Mean	Std. Dev.	Min	Max
tprectal	128	37.95234	1.082863	35.9	40.4

```
. sum tprectal if agegrp == 3
```

Variable	Obs	Mean	Std. Dev.	Min	Max
tprectal	320	38.07356	1.16561	35.6	41.2

```
. sum tprectal if agegrp == 4
```

Variable	Obs	Mean	Std. Dev.	Min	Max
tprectal	169	37.91006	1.077124	35.7	40.6

```
. sum tprectal if agegrp == 5
```

Variable	Obs	Mean	Std. Dev.	Min	Max
tprectal	135	37.63556	1.024438	34.9	40.5

```
. sum tprectal if agegrp == 6
```

Variable	Obs	Mean	Std. Dev.	Min	Max
tprectal	107	37.4271	1.095322	34.5	40.9

```
.  
. sum tpore if agegrp == 1
```

Variable	Obs	Mean	Std. Dev.	Min	Max
tpore	136	37.21324	.7833271	35.8	40.5

```
. sum tpore if agegrp == 2
```

Variable	Obs	Mean	Std. Dev.	Min	Max
tpore	128	37.95391	1.078122	36	40.9

```
. sum tpore if agegrp == 3
```

Variable	Obs	Mean	Std. Dev.	Min	Max
tpore	320	38.08531	1.134692	35.5	41.1

```
. sum tpore if agegrp == 4
```

Variable	Obs	Mean	Std. Dev.	Min	Max
tpore	169	38.1	1.030372	36	41.1

```
. sum tpore if agegrp == 5
```

Variable	Obs	Mean	Std. Dev.	Min	Max
tpore	135	37.81481	.9723428	36	41

```
. sum tpore if agegrp == 6
```

Variable	Obs	Mean	Std. Dev.	Min	Max
tpore	107	37.4757	.9783352	35	40.9

```
.  
end of do-file  
.
```

We conclude, that due to the higher standard deviation than expected, our study size where 104-169 children were included in the subgroups will only have a 90% power to detect significant differences higher than 0.4- 0.45 °C instead of 0.3 °C.

The screenshot shows the OpenEpi calculator interface. The left sidebar contains a tree view of various statistical tools. The main window displays the 'Sample Size For Comparing Two Means' calculator. The 'Input Data' section is highlighted in cyan and shows: Confidence Interval (2-sided) 95%, Power 90%, and Ratio of sample size (Group 2/Group 1) 1. Below this, a table shows the input parameters for Group 1 and Group 2, with a difference of 0.45. The resulting sample sizes are 104 for each group, totaling 208.

	Group 1	Group 2	Difference*
Mean			0.45
Standard deviation	1	1	
Variance	1	1	

Sample size of Group 1	104
Sample size of Group 2	104
Total sample size	208

*Difference between the means

Results from OpenEpi, Version 3, open source calculator--SSMean
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The screenshot shows the OpenEpi calculator interface. The left sidebar contains a tree view of various statistical tools. The main window displays the 'Sample Size For Comparing Two Means' calculator. The 'Input Data' section is highlighted in cyan and shows: Confidence Interval (2-sided) 95%, Power 90%, and Ratio of sample size (Group 2/Group 1) 1. Below this, a table shows the input parameters for Group 1 and Group 2, with a difference of 0.4. The resulting sample sizes are 132 for each group, totaling 264.

	Group 1	Group 2	Difference*
Mean			0.4
Standard deviation	1	1	
Variance	1	1	

Sample size of Group 1	132
Sample size of Group 2	132
Total sample size	264

*Difference between the means

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