

Dataset Integrity Check for the  
Cysteamine Bitartrate Delayed-Release  
for the Treatment of Nonalcoholic Fatty  
Liver Disease (NAFLD) in Children (CyNCh)  
Data Files

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August 11, 2020

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## 1 Standard Disclaimer

The intent of this DSIC is to provide confidence that the data distributed by the NIDDK repository is a true copy of the study data. Our intent is not to assess the integrity of the statistical analyses reported by study investigators. As with all statistical analyses of complex datasets, complete replication of a set of statistical results should not be expected in secondary analysis. This occurs for a number of reasons including differences in the handling of missing data, restrictions on cases included in samples for a particular analysis, software coding used to define complex variables, etc. Experience suggests that most discrepancies can ordinarily be resolved by consultation with the study data coordinating center (DCC), however this process is labor-intensive for both DCC and Repository staff. It is thus not our policy to resolve every discrepancy that is observed in an integrity check. Specifically, we do not attempt to resolve minor or inconsequential discrepancies with published results or discrepancies that involve complex analyses, unless NIDDK Repository staff suspect that the observed discrepancy suggests that the dataset may have been corrupted in storage, transmission, or processing by repository staff. We do, however, document in footnotes to the integrity check those instances in which our secondary analyses produced results that were not fully consistent with those reported in the target publication.

## 2 Study Background

The CyNCh (Cysteamine Bitartrate Delayed-Release for the Treatment of NAFLD in Children) study is a prospective, multicenter, double-blind clinical trial designed by the NASH Clinical Research Network to determine whether treatment with cysteamine improves disease severity in children diagnosed with NAFLD. Children between the ages of 8 and 17 years with biopsy-confirmed moderate to severe NAFLD were eligible for the CyNCh study. Participants were enrolled and randomized to treatment with either delayed-release cysteamine bitartrate capsules or placebo capsules. Improvement in NAFLD at 52 weeks, defined as a decrease in NAFLD Activity Score (NAS) of at least 2 and no worsening of fibrosis, was assessed as the primary outcome measure. Secondary outcome measures, assessed at 52 weeks, included reduction in serum aminotransferase and gamma-glytamyl transpeptidase, reduction in MRI-determined hepatic fat fraction, changes in markers of oxidation and anti-oxidant status, changes in histology and symptoms, and self-reported quality of life.

## 3 Archived Datasets

All SAS data files, as provided by the Data Coordinating Center (DCC), are located in the data package. For this replication, variables were taken from the various analysis datasets.

## 4 Statistical Methods

Analyses were performed to duplicate results for the data published by Schwimmer et al in Gastroenterology in 2016 [1].

To verify the integrity of the three datasets, descriptive statistics were computed.

## 5 Results

For Table 1 in the publication [1], Baseline Characteristics of the Study Population were examined. Table A lists the variables that were used in the replication and Table B compares the results calculated from the archived data file to the results published in Table 1. The results of the replication are an exact match to the published results.

## 6 Conclusions

The NIDDK repository is confident that the CyNCh data files to be distributed are a copy of the manuscript data.

## 7 References

[1] Schwimmer, J.B., Lavine, J.E., Wilson, L.A., Neuschwander-Tetri, B.A., Xanthakos, S.A., Kohli, R., Barlow, S.E., Vos, M.B., Karpen, S.J., Molleston, J.P., Whittington, P.F., Rosenthal, P., Jain, A.K., Murray, K.F., Brunt, E.M., Kleiner, D.E., Van Natta, M.L., Clark, J.M., Tonascia, J., Doo, E., and the NASH CRN. In Children With Nonalcoholic Fatty Liver Disease, Cysteamine Bitartrate Delayed Release Improves Liver Enzymes but Does Not Reduce Disease Activity Scores. *Gastroenterology* 2016;151:1141-1154.

Table A: Variables used to replicate Table 1: Baseline Characteristics of the Study Population

<b>Table Variable</b>	<b>dataset.variable</b>
Weight stratum	table1.wt_strat
Age, y	table1.age
Male	table1.gender
Race	table1.race
Hispanic ethnicity	table1.hispanic
Self-reported pediatric QOL Physical health	table1.cphys
Self-reported pediatric QOL Psychosocial health	table1.csoc
Parent/guardian-reported pediatric QOL Physical health	table1.pphys
Parent/guardian-reported pediatric QOL Psychosocial health	table1.psoc
Alanine aminotransferase, U/L	table1.alt
Aspartate aminotransferase, U/L	table1.ast
Alkaline phosphatase, U/L	table1.alkphos
Gamma-glutamyl transpeptidase, U/L	table1.ggt
Total bilirubin, mg/dL	table1.bilitot
Total cholesterol, mg/dL	table1.totchol
HDL cholesterol, mg/dL	table1.hdl
LDL cholesterol, mg/dL	table1.ldl
Non-HDL cholesterol, mg/dL	table1.nonhdlc
Triglycerides, mg/dL	table1.triglyc
Weight, kg	table1.wtkg
Body mass index, kg/m <sup>2</sup>	table1.bmi
Body mass index z-score	table1.bmiz
Waist circumference, cm	table1.waistcm
Fasting serum glucose, mg/dL	table1.glucose
Insulin, uU/mL	table1.insulin
HOMA-IR (glucose [mmol/L] x insulin [pmol/L]/22.5)	table1.homa
Systolic blood pressure, mm Hg	table1.systolic
Diastolic blood pressure, mm Hg	table1.diastoli
Diabetes	table1.diabetes
Hypertension	table1.hyperten
Hyperlipidemia	table1.hyperlip
NAFLD activity score	table1.bnas
Steatosis score	table1.bsteato
Lobular inflammation score	table1.blobinf
Hepatocellular ballooning score	table1.bball
Portal inflammation score	table1.bportinf
Fibrosis stage (0, 1a, 1b, 1c, 2, 3, 4)	table1.bfib

<b>Table Variable</b>	<b>dataset.variable</b>
Fibrosis stage (0, 1, 2, 3, 4)	table1.bfibro
Steatohepatitis	table1.bstdiag
Treatment	table1.tx

Table B-1: Comparison of values computed in integrity check to reference article Table 1 values (CBDR and Placebo)

	CBDR (N=88) Manuscript N (%) unless noted*	CBDR (N=88) DSIC	Diff. (N=0)	Placebo (N=81) Manuscript N (%) unless noted*	Placebo (N=81) DSIC	Diff. (N=0)
Weight stratum						
≤65 kg	24 (27%)	24 (27%)	0 (0%)	23 (28%)	23 (28%)	0 (0%)
>65 to 80 kg	14 (16%)	14 (16%)	0 (0%)	10 (12%)	10 (12%)	0 (0%)
>80 kg	50 (57%)	50 (57%)	0 (0%)	48 (59%)	48 (59%)	0 (0%)
Demographics						
Age, y*	13.8 (2.9)	13.8 (2.9)	0 (0)	13.6 (2.5)	13.6 (2.5)	0 (0)
Male	63 (72%)	63 (72%)	0 (0%)	56 (69%)	56 (69%)	0 (0%)
Race						
American Indian/Alaska Native	5 (6%)	5 (6%)	0 (0%)	6 (7%)	6 (7%)	0 (0%)
Asian	0 (0%)	0 (0%)	0 (0%)	2 (2%)	2 (2%)	0 (0%)
Black or African American	3 (3%)	3 (3%)	0 (0%)	3 (4%)	3 (4%)	0 (0%)
White	56 (64%)	56 (64%)	0 (0%)	46 (57%)	46 (57%)	0 (0%)
More than 1 race	3 (3%)	3 (3%)	0 (0%)	1 (1%)	1 (1%)	0 (0%)
Refusal/not stated	21 (24%)	21 (24%)	0 (0%)	23 (28%)	23 (28%)	0 (0%)
Hispanic ethnicity	66 (75%)	66 (75%)	0 (0%)	58 (72%)	58 (72%)	0 (0%)
Self-reported pediatric QOL						
Physical health*	81 (15)	81 (15)	0 (0)	82 (19)	82 (19)	0 (0)
Psychosocial health*	75 (16)	75 (16)	0 (0)	77 (16)	77 (16)	0 (0)
Parent/guardian-reported pediatric QOL						
Physical health*	68 (21)	68 (21)	0 (0)	69 (24)	69 (24)	0 (0)
Psychosocial health*	67 (19)	67 (19)	0 (0)	68 (18)	68 (18)	0 (0)
Liver enzyme levels						
Alanine aminotransferase, U/L						
Median (IQR)*	93 (67-175)	93 (67-175)	0 (0-0)	80 (61-120)	80 (61-120)	0 (0-0)
Mean (SD)*	140 (118)	140 (118)	0 (0)	103 (76)	103 (76)	0 (0)
Aspartate aminotransferase, U/L						
Median (IQR)*	55 (40-91)	55 (40-91)	0 (0-0)	49 (38-69)	49 (38-69)	0 (0-0)
Mean (SD)*	82 (71)	82 (71)	0 (0)	59 (38)	59 (38)	0 (0)
Alkaline phosphatase, U/L*	224 (116)	224 (116)	0 (0)	214 (101)	214 (101)	0 (0)

	CBDR (N=88) Manuscript N (%) unless noted*	CBDR (N=88) DSIC	Diff. (N=0)	Placebo (N=81) Manuscript N (%) unless noted*	Placebo (N=81) DSIC	Diff. (N=0)
Gamma-glutamyl transpeptidase, U/L*	50 (33)	50 (33)	0 (0)	44 (29)	44 (29)	0 (0)
Total bilirubin, mg/dL*	0.54 (0.34)	0.54 (0.34)	0 (0)	0.50 (0.26)	0.50 (0.26)	0 (0)
Lipids						
Total cholesterol, mg/dL*	165 (40)	165 (40)	0 (0)	163 (37)	163 (37)	0 (0)
HDL cholesterol, mg/dL*	39 (9)	39 (9)	0 (0)	41 (9)	41 (9)	0 (0)
LDL cholesterol, mg/dL*	95 (32)	95 (32)	0 (0)	92 (31)	92 (31)	0 (0)
Non-HDL cholesterol, mg/dL*	126 (40)	126 (40)	0 (0)	122 (37)	122 (37)	0 (0)
Triglycerides, mg/dL*	160 (81)	160 (81)	0 (0)	157 (77)	157 (77)	0 (0)
Metabolic factors						
Weight, kg*	85 (26)	85 (26)	0 (0)	84 (25)	84 (25)	0 (0)
Body mass index, kg/m <sup>2</sup> *	33 (7)	33 (7)	0 (0)	32 (6)	32 (6)	0 (0)
Body mass index z-score*	2.2 (0.5)	2.2 (0.5)	0 (0)	2.2 (0.4)	2.2 (0.4)	0 (0)
Waist circumference, cm*	104 (15)	104 (15)	0 (0)	103 (15)	103 (15)	0 (0)
Fasting serum glucose, mg/dL*	87 (10)	87 (10)	0 (0)	88 (14)	88 (14)	0 (0)
Insulin, uU/mL*	35 (31)	35 (31)	0 (0)	38 (34)	38 (34)	0 (0)
HOMA-IR (glucose [mmol/L] x insulin [pmol/L]/22.5)*	7.7 (7.5)	7.7 (7.5)	0 (0)	8.4 (7.7)	8.4 (7.7)	0 (0)
Systolic blood pressure, mm Hg*	120 (11)	120 (11)	0 (0)	120 (12)	120 (12)	0 (0)
Diastolic blood pressure, mm Hg*	68 (8)	68 (8)	0 (0)	67 (10)	67 (10)	0 (0)
Comorbidities						
Diabetes	1 (1%)	1 (1%)	0 (0%)	7 (9%)	7 (9%)	0 (0%)
Hypertension	9 (10%)	9 (10%)	0 (0%)	6 (7%)	6 (7%)	0 (0%)
Hyperlipidemia	13 (15%)	13 (15%)	0 (0%)	12 (15%)	12 (15%)	0 (0%)
Liver histology findings						
NAFLD activity score*	4.7 (1.4)	4.7 (1.4)	0 (0)	4.6 (1.4)	4.6 (1.4)	0 (0)
Steatosis score*	2.3 (0.8)	2.3 (0.8)	0 (0)	2.5 (0.7)	2.5 (0.7)	0 (0)
Lobular inflammation score*	1.8 (0.7)	1.8 (0.7)	0 (0)	1.6 (0.7)	1.6 (0.7)	0 (0)
Hepatocellular ballooning score*	0.6 (0.7)	0.6 (0.7)	0 (0)	0.6 (0.8)	0.6 (0.8)	0 (0)
Portal inflammation score*	1.1 (0.5)	1.1 (0.5)	0 (0)	1.1 (0.5)	1.1 (0.5)	0 (0)
Fibrosis stage						
0, none	24 (27%)	24 (27%)	0 (0%)	25 (31%)	25 (31%)	0 (0%)

	CBDR (N=88) Manuscript N (%) unless noted*	CBDR (N=88) DSIC	Diff. (N=0)	Placebo (N=81) Manuscript N (%) unless noted*	Placebo (N=81) DSIC	Diff. (N=0)
1a, mild, zone 3 perisinusoidal	9 (10%)	9 (10%)	0 (0%)	7 (9%)	7 (9%)	0 (0%)
1b, moderate, zone 3 perisinusoidal	6 (7%)	6 (7%)	0 (0%)	5 (6%)	5 (6%)	0 (0%)
1c, portal/periportal only	20 (23%)	20 (23%)	0 (0%)	20 (25%)	20 (25%)	0 (0%)
2, zone 3 and periportal, any combination	9 (10%)	9 (10%)	0 (0%)	13 (16%)	13 (16%)	0 (0%)
3, bridging	19 (22%)	19 (22%)	0 (0%)	11 (14%)	11 (14%)	0 (0%)
4, cirrhosis	1 (1%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Fibrosis stage*	1.3 (1.1)	1.3 (1.1)	0 (0)	1.1 (1.0)	1.1 (1.0)	0 (0)
Steatohepatitis						
No	25 (28%)	25 (28%)	0 (0%)	19 (23%)	19 (23%)	0 (0%)
Borderline zone 3 pattern	16 (18%)	16 (18%)	0 (0%)	10 (12%)	10 (12%)	0 (0%)
Borderline zone 1 pattern	23 (26%)	23 (16%)	0 (0%)	29 (36%)	29 (36%)	0 (0%)
Definite	24 (27%)	24 (27%)	0 (0%)	23 (28%)	23 (28%)	0 (0%)

\*denotes mean (standard deviation)

Table B-2: Comparison of values computed in integrity check to reference article Table 1 values (Total)

	Total (N=169) Manuscript N (%) unless noted*	Total (N=169) DSIC	Diff. (N=0)
Weight stratum			
≤65 kg	47 (28%)	47 (28%)	0 (0%)
>65 to 80 kg	24 (14%)	24 (14%)	0 (0%)
>80 kg	98 (58%)	98 (58%)	0 (0%)
Demographics			
Age, y*	13.7 (2.7)	13.7 (2.7)	0 (0)
Male	119 (70%)	119 (70%)	0 (0%)
Race			
American Indian/Alaska Native	11 (7%)	11 (7%)	0 (0%)
Asian	2 (1%)	2 (1%)	0 (0%)
Black or African American	6 (4%)	6 (4%)	0 (0%)
White	102 (60%)	102 (60%)	0 (0%)
More than 1 race	4 (2%)	4 (2%)	0 (0%)
Refusal/not stated	44 (26%)	44 (26%)	0 (0%)
Hispanic ethnicity	124 (73%)	124 (73%)	0 (0%)
Self-reported pediatric QOL			
Physical health*	81 (17)	81 (17)	0 (0)
Psychosocial health*	76 (16)	76 (16)	0 (0)
Parent/guardian-reported pediatric QOL			
Physical health*	68 (23)	68 (23)	0 (0)
Psychosocial health*	68 (19)	68 (19)	0 (0)
Liver enzyme levels			
Alanine aminotransferase, U/L			
Median (IQR)*	87 (62-151)	87 (62-151)	0 (0-0)
Mean (SD)*	123 (101)	123 (101)	0 (0)
Aspartate aminotransferase, U/L			
Median (IQR)*	52 (39-79)	52 (39-79)	0 (0-0)
Mean (SD)*	71 (59)	71 (59)	0 (0)
Alkaline phosphatase, U/L*	220 (109)	220 (109)	0 (0)
Gamma-glutamyl transpeptidase, U/L*	47 (31)	47 (31)	0 (0)

	Total (N=169) Manuscript N (%) unless noted*	Total (N=169) DSIC	Diff. (N=0)
Total bilirubin, mg/dL*	0.52 (0.30)	0.52 (0.30)	0 (0)
Lipids			
Total cholesterol, mg/dL*	164 (38)	164 (38)	0 (0)
HDL cholesterol, mg/dL*	40 (9)	40 (9)	0 (0)
LDL cholesterol, mg/dL*	94 (31)	94 (31)	0 (0)
Non-HDL cholesterol, mg/dL*	124 (39)	124 (39)	0 (0)
Triglycerides, mg/dL*	158 (79)	158 (79)	0 (0)
Metabolic factors			
Weight, kg*	85 (25)	85 (25)	0 (0)
Body mass index, kg/m <sup>2</sup> *	32 (6)	32 (6)	0 (0)
Body mass index z-score*	2.2 (0.4)	2.2 (0.4)	0 (0)
Waist circumference, cm*	103 (15)	103 (15)	0 (0)
Fasting serum glucose, mg/dL*	88 (12)	88 (12)	0 (0)
Insulin, uU/mL*	36 (32)	36 (32)	0 (0)
HOMA-IR (glucose [mmol/L] x insulin [pmol/L]/22.5)*	8.0 (7.6)	8.0 (7.6)	0 (0)
Systolic blood pressure, mm Hg*	120 (11)	120 (11)	0 (0)
Diastolic blood pressure, mm Hg*	67 (9)	67 (9)	0 (0)
Comorbidities			
Diabetes	8 (5%)	8 (5%)	0 (0%)
Hypertension	15 (9%)	15 (9%)	0 (0%)
Hyperlipidemia	25 (15%)	25 (15%)	0 (0%)
Liver histology findings			
NAFLD activity score*	4.7 (1.4)	4.7 (1.4)	0 (0)
Steatosis score*	2.4 (0.7)	2.4 (0.7)	0 (0)
Lobular inflammation score*	1.7 (0.7)	1.7 (0.7)	0 (0)
Hepatocellular ballooning score*	0.6 (0.7)	0.6 (0.7)	0 (0)
Portal inflammation score*	1.1 (0.5)	1.1 (0.5)	0 (0)
Fibrosis stage			
0, none	49 (29%)	49 (29%)	0 (0%)
1a, mild, zone 3 perisinusoidal	16 (9%)	16 (9%)	0 (0%)

	Total (N=169) Manuscript N (%) unless noted*	Total (N=169) DSIC	Diff. (N=0)
1b, moderate, zone 3 perisinusoidal	11 (7%)	11 (7%)	0 (0%)
1c, portal/periportal only	40 (24%)	40 (24%)	0 (0%)
2, zone 3 and periportal, any combination	22 (13%)	22 (13%)	0 (0%)
3, bridging	30 (18%)	30 (18%)	0 (0%)
4, cirrhosis	1 (1%)	1 (1%)	0 (0%)
Fibrosis stage*	1.2 (1.1)	1.2 (1.1)	0 (0)
Steatohepatitis			
No	44 (26%)	44 (26%)	0 (0%)
Borderline zone 3 pattern	26 (15%)	26 (15%)	0 (0%)
Borderline zone 1 pattern	52 (31%)	52 (31%)	0 (0%)
Definite	47 (28%)	47 (28%)	0 (0%)

\*denotes mean (standard deviation)

## Appendix A: SAS Code

```
*** CyNCh DSIC;

proc format;
  value yesnof 0 = 'No'
    1 = 'Yes';
  value genderf 1 = 'Male'
    2 = 'Female';
  value weightf 1 = '<= 65 kg'
    2 = '>65 to 80 kg'
    3 = '>80 kg';
  value $steatf '0' = 'No'
    '1a' = 'Borderline zone 3 pattern'
    '1b' = 'Borderline zone 1 pattern'
    '2' = 'Definite';
  value $racef 'AmInd' = 'American Indian/Alaska Native'
    'Asian' = 'Asian'
    'Black' = 'Black or African American'
    'White' = 'White'
    'Multi' = 'More than 1 race'
    'Ref' = 'Refusal/not stated';
  value groupf 0 = 'Placebo'
    1 = 'CBDR';
  value wtf 0 = '<= 65 kg at baseline'
    1 = '>65 kg at baseline';

libname sas_data '/prj/niddk/ims_analysis/CyNCh/private_created_data/SAS_DATA/';

data table1;
  set sas_data.table1;

proc contents data = table1;

proc freq data = table1;
  tables tx;
  title 'Table 1 - TX';

proc sort data = table1;
  by tx;

proc freq data = table1;
  tables wt_strat;
  format wt_strat weightf.;
  by tx;
  title 'Table 1 - Weight stratum';

proc freq data = table1;
  tables wt_strat;
  format wt_strat weightf.;

proc means data = table1 n mean std;
  var age;
  class tx;
  types () tx;
```

```

        title 'Table 1 - Age';

proc freq data = table1;
    tables gender;
    format gender genderf.;
    by tx;
    title 'Table 1 - Gender';

proc freq data = table1;
    tables gender;
    format gender genderf.;

proc freq data = table1;
    tables race;
    format race $racef.;
    by tx;
    title 'Table 1 - Race';

proc freq data = table1;
    tables race;
    format race $racef.;

proc freq data = table1;
    tables hispanic;
    format hispanic yesnof.;
    by tx;
    title 'Table 1 - Hispanic ethnicity';

proc freq data = table1;
    tables hispanic;
    format hispanic yesnof.;

proc means data = table1 n mean std;
    var cphys;
    class tx;
    types () tx;
    title 'Table 1 - Self-reported pediatric QOL Physical health';

proc means data = table1 n mean std;
    var csoc;
    class tx;
    types () tx;
    title 'Table 1 - Self-reported pediatric QOL Psychosocial health';

proc means data = table1 n mean std;
    var pphys;
    class tx;
    types () tx;
    title 'Table 1 - Parent/guardian-reported pediatric QOL Physical health';

proc means data = table1 n mean std;
    var psoc;
    class tx;
    types () tx;
    title 'Table 1 - Parent/guardian-reported pediatric QOL Psychosocial health';

```

```

proc means data = table1 n median p25 p75 mean std;
  var alt;
  class tx;
  types () tx;
  title 'Table 1 - Alanine aminotransferase';

proc means data = table1 n median p25 p75 mean std;
  var ast;
  class tx;
  types () tx;
  title 'Table 1 - Aspartate aminotransferase';

proc means data = table1 n mean std;
  var alkphos;
  class tx;
  types () tx;
  title 'Table 1 - Alkaline phosphatase';

proc means data = table1 n mean std;
  var ggt;
  class tx;
  types () tx;
  title 'Table 1 - GGT';

proc means data = table1 n mean std;
  var bilitot;
  class tx;
  types () tx;
  title 'Table 1 - Total bilirubin';

proc means data = table1 n mean std;
  var totchol;
  class tx;
  types () tx;
  title 'Table 1 - Total cholesterol';

proc means data = table1 n mean std;
  var hdl;
  class tx;
  types () tx;
  title 'Table 1 - HDL cholesterol';

proc means data = table1 n mean std;
  var ldl;
  class tx;
  types () tx;
  title 'Table 1 - LDL cholesterol';

proc means data = table1 n mean std;
  var nonhdlc;
  class tx;
  types () tx;
  title 'Table 1 - Non-HDL cholesterol';

proc means data = table1 n mean std;
  var triglyc;

```

```

class tx;
types () tx;
title 'Table 1 - Triglycerides';

proc means data = table1 n mean std;
var wtkg;
class tx;
types () tx;
title 'Table 1 - Weight';

proc means data = table1 n mean std;
var bmi;
class tx;
types () tx;
title 'Table 1 - BMI';

proc means data = table1 n mean std;
var bmiz;
class tx;
types () tx;
title 'Table 1 - BMI z-score';

proc means data = table1 n mean std;
var waistcm;
class tx;
types () tx;
title 'Table 1 - Waist circumference';

proc means data = table1 n mean std;
var glucose;
class tx;
types () tx;
title 'Table 1 - Fasting serum glucose';

proc means data = table1 n mean std;
var insulin;
class tx;
types () tx;
title 'Table 1 - Insulin';

proc means data = table1 n mean std;
var homa;
class tx;
types () tx;
title 'Table 1 - HOMA-IR';

proc means data = table1 n mean std;
var systolic;
class tx;
types () tx;
title 'Table 1 - Systolic blood pressure';

proc means data = table1 n mean std;
var diastoli;
class tx;
types () tx;

```

```

    title 'Table 1 - Diastolic blood pressure';

proc freq data = table1;
    tables diabetes;
    format diabetes yesnof.;
    by tx;
    title 'Table 1 - Diabetes';

proc freq data = table1;
    tables diabetes;
    format diabetes yesnof.;

proc freq data = table1;
    tables hyperten;
    format hyperten yesnof.;
    by tx;
    title 'Table 1 - Hypertension';

proc freq data = table1;
    tables hyperten;
    format hyperten yesnof.;

proc freq data = table1;
    tables hyperlip;
    format hyperlip yesnof.;
    by tx;
    title 'Table 1 - Hyperlipidemia';

proc freq data = table1;
    tables hyperlip;
    format hyperlip yesnof.;

proc means data = table1 n mean std;
    var bnas;
    class tx;
    types () tx;
    title 'Table 1 - NAFLD Activity score';

proc means data = table1 n mean std;
    var bsteato;
    class tx;
    types () tx;
    title 'Table 1 - Steatosis score';

proc means data = table1 n mean std;
    var blobinf;
    class tx;
    types () tx;
    title 'Table 1 - Lobular inflammation score';

proc means data = table1 n mean std;
    var bball;
    class tx;
    types () tx;
    title 'Table 1 - Hepatocellular ballooning score';

```

```
proc means data = table1 n mean std;  
  var bportinf;  
  class tx;  
  types () tx;  
  title 'Table 1 - Portal inflammation score';
```

```
proc freq data = table1;  
  tables bfib;  
  by tx;  
  title 'Table 1 - Fibrosis stage';
```

```
proc freq data = table1;  
  tables bfib;
```

```
proc means data = table1 n mean std;  
  var bfibro;  
  class tx;  
  types () tx;  
  title 'Table 1 - Fibrosis stage';
```

```
proc freq data = table1;  
  tables bstdiag;  
  format bstdiag $steatf. ;  
  by tx;  
  title 'Table 1 - Steatohepatitis';
```

```
proc freq data = table1;  
  tables bstdiag;  
  format bstdiag $steatf. ;
```